# Exhibit 75

# The relationship between perineal cosmetic talc usage and ovarian talc particle burden

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OBJECTIVE: Epidemiologic studies support the hypothesis of a dose-related risk of epithelial ovarian cancer with perineal talc exposure. Frequency and duration of talc usage has not been previously correlated with ovarian talc content.

STUDY DESIGN: Ovaries were studied from 24 women undergoing incidental oophorectomy who were interviewed regarding talc usage. Twelve subjects reported frequent perineal talc applications; the twelve controls reported no use. Ovarian tissue blocks were digested and analyzed by polarized light microscopy and analytic electron microscopy to identify and quantify talc.

RESULTS: Talc was identified in all 24 cases by either light or electron microscopy. Talc particle counts were completely unrelated to reported levels of perineal talc exposure.

CONCLUSIONS: The detection of talc in all ovaries demonstrates that it can reach the upper genital tract. Widespread exposure to talc during diapering may contribute to the ubiquitous presence of talc in ovarian tissue. (Am J OBSTET GYNECOL 1996;174:1507-10.)

**Key words:** Talc, ovary

Epidemiologic evidence suggests that perineal exposure to talc is associated with an increased risk of epithelial ovarian cancer in a dose-related fashion.1-5 Other epidemiologic studies have shown no increased risk of ovarian cancer associated with talc.6, 7 Studies show access of particulate matter into the female peritoneal cavity through the transvaginal route. 8-10 A few reports have identified talc in ovarian tissue, 11, 12 both benign and malignant, but these data were not correlated with an exposure history. Other potential genital tract exposures in a woman's life include surgical gloves,13 condoms, and diaphragms. Diapering with talc during infancy is another potential exposure. Epidemiologic studies have not linked these exposures to an increased risk of ovarian cancer. 1, 2

If transvaginal transport of perineally applied talc occurs, women with the heaviest exposures may show the largest talc particle burdens in their ovaries. Tissue digestion techniques are an accepted analytic adjunct in the identification and quantification of asbestos in the lungs of occupationally exposed individuals14, 15 and are useful in the identification and quantification of talc as well.

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The goal of this pathoepidemiologic study was to correlate the history of perineal talc usage with the talc particle burden found in the ovaries.

#### Material and methods

In a case control study of benign ovarian neoplasms at Columbia Presbyterian Medical Center, women undergoing surgery from 1992 to 1993 were interviewed regarding various factors, including talc usage. Subjects were also questioned regarding possible occupational exposures to asbestos, and mothers were contacted regarding diapering history whenever feasible.

Subjects were categorized for talc exposures as follows. Women who reported no direct application of talc to the perineum or to underwear were considered unexposed. For women who reported talc application to underwear or the perineum, the total number of lifetime applications was estimated as the average frequency of use times the number of years of use. For instance, a woman who reported perineal talc application twice per day for 10 years was considered to have 7240 applications. To simplify the classification of exposed and unexposed women, subjects who reported tubal ligation, diaphragm use, or feminine hygiene spray use were excluded from this analysis.

Interviewed subjects from the parent case control study who had a normal contralateral ovary in the surgical specimen were eligible for this substudy. Sections of normal ovary from the 12 women who reported the largest number of perineal talc applications were analyzed. For each of these subjects the unexposed woman closest in age was selected as a control. In addition, the ovaries of two stillborn fetuses were analyzed as negative controls.

Table I. Talc particle counts in women who reported perineal cosmetic talc usage

Subject No.	age (yr)	Lifetime talc applications*	EM talc particle counts†	Polarized light microscopic counts†	Asbestos detected	Talc use with diapering
1	49	4,784	1,600,288	96	No	Yes
2	49	5,475	0	54	No	Unknown
3	57	6,552	0	100	Yes	No
4	31	8,144	0	114	No	Unknown
5	43	10,556	0	464	Yes	Unknown
6	45	11,284	151,300	300	No	Yes
7	50	11,648	236,406	345	No	Yes
8	57	15,600	0	75	No	Yes
9	66	18,980	0	250	Yes	Yes
10	47	21,840	1,576,000	111	No	Unknown
11	44	23,660	0	348	No	Yes
12	44	39,312	7,565,000	26	Yes	Unknown

EM, Electron microscopy.

Ovarian tissue in blocks was deparaffinized, rehydrated, blotted dry, and weighed. Digestion with 5% potassium hydroxide was performed at 70° C for 2 to 4 hours. After complete digestion, the tissue was centrifuged at 12,000 revolutions/min for 20 minutes. The potassium hydroxide was removed, leaving a pellet to which approximately 20 ml of distilled water was added. The pellet was resuspended by use of a microultrasonic cell disrupter at 50 W for 5 seconds. Centrifugation, distilled water wash, and microultrasonic cell disrupter were repeated three times. The distilled water was removed, and the pellet was resuspended in 5 to 10 ml of distilled water. Drops of 10 µl of the final suspension were placed on nickel formvar and carbon-coated locator grids and air-dried. Transmission electron microscopy to identify particles and their size was performed. The identity of the particles was determined by energy-dispersive spectroscopy and confirmed by electron diffraction. Grids were viewed at both 10,000 and 19,000 diameters. All talc particles observed were counted. Cytospin slides for polarized light microscopy were prepared from the same final suspension as the electron microscopy grids. Polarized light microscopy counted larger talc particles (limits of detection approximately 1 µm), whereas electron microscopy detected smaller ones (limits of detection approximately 0.5 nm).

Routinely, all solutions are checked for detectable limits of contaminating particles; all places where particles could have contaminated the specimen, such as paraffin, are also controlled for.

Associations between talc exposure and talc particle count in the 12 exposed subjects were assessed with Spearman's rank correlation coefficient.

#### Results

Detailed results can be seen in Tables I and II. The mean age of the patients was 49 years (range 29 to 66

years). For eight exposed subjects, a control was found who was within 4 years of her age. Talc particle counts were not related to age in either the exposed or unexposed subjects (p > 0.25). The mean number of lifetime exposures for the women reporting perineal talc use was 14,820 (range 4784 to 39,312). Talc was detected in all ovaries by either polarized light or electron microscopy. There was a wide range of values, as shown by the large SDs. Table III shows that talc particles were observed to a similar extent with both exposed and unexposed subjects.

Neither the light microscopic nor electron microscopic values correlated with reported perineal talc usage (p values 0.37 and 0.45). There was a negative correlation between the values obtained by light microscopy and electron microscopy (r=-0.34, p=0.05). An attempt to contact mothers of subjects was successful for 11 of the 24 subjects. Ten of these reported using talc to diaper their babies, which indicates that lifetime talc exposure may be underestimated for nearly all the subjects. Analyses of two fetal ovaries and a pair of surgical gloves was completely negative for talc.

In one subject we studied both ovaries; on the right side we detected no talc by electron microscopy and 556 particles by light microscopy, and on the left side we detected 1,669,000 particles per gram of wet weight by electron microscopy and 6 particles by light microscopy. Hematoxylin-eosin stained slides from the analyzed sections of tissue were examined. There was no evidence of response to talc, such as foreign body giant cell reactions or fibrosis in the tissue. Asbestos was detected in ovaries of five of the subjects with no talc exposure and in four ovaries of the talc-exposed subjects.

#### Comment

If transvaginal transport of perineally applied talc occurs, we would expect women with the heaviest exposures to show the largest talc particle burden in their ovaries.

<sup>\*</sup>Frequency of use × Years of use.

<sup>†</sup>Per gram wet tissue weight.

Table II. Talc particle counts in women without history of perineal cosmetic talc usage

Subject No.	Age (yr)	Reported exposure history	EM talc particle count*	Polarized light microscopic talc particle counts*	Asbestos detected	Talc use with diapering
1	63	0	1,350,000	89	No	Yes
2	57	0	315,250	111	No	Yes
3	29	0	0	42	No	Unknown
4	48	0	1,669,000	6	Yes	Unknown
5	59	0	315,208	166	Yes	Yes
6	40	0	0	69	Yes	Yes
7	43	0	0	566	Yes	Unknown
8	64	0	0	420	Yes	Yes
9	49	0	0	53	No	Unknown
10	54	0	0	1139	No	Unknown
11	32	0	63,042	2200	No	Unknown
12	58	0	472,813	0	No	Unknown

EM, Electron microscopy.

Table III. Comparison of particle burdens between reported exposed and nonexposed subjects

Talc exposure	No. of subjects with talc by EM	No. of subjects with talc by light microscopy	Mean EM particle count*	SD	Mean light microscopic particle count*	SD
Reported talc use $(n=12)$	5/12	12/12	927,416	2,174,888	190	144
No reported talc use $(n=12)$	6/12	11/12	348,776	570,055	405	655

EM, Electron microscopy.

Tissue digestion techniques have been used to identify and quantify particle burdens of various organic materials in human tissue. The most notable use of this technique is in the identification of asbestos in the lungs of occupationally exposed individuals. <sup>14, 15</sup> Other studies have examined other organs as well. In the 1979 report of Henderson et al. <sup>11</sup> ovaries were studied after an oxygen incineration procedure. They found 6900 to 55,100 talc particles per gram of wet weight in three normal ovaries, 17,400 to 24,300 in three cystic ovaries, and 6400 to 24,500 in three ovarian adenocarcinomas. No exposure histories were stated.

Our study attempted to correlate ovarian talc particle burden with exposure history. Our results do not support a linear dose-related ovarian talc particle burden. However, the mean electron microscopic particle count was much higher in talc users. Perhaps perineal talc does contribute to the ovarian particle burden; however, factors other than dosage may contribute. Other factors to consider include method of application, type of talc, and the possible contribution of inhaled talc particles. The range of talc particle values obtained in this study was wide, as evidenced by the large SDs. This spread of values was also present in the study of Henderson et al. 11 and in much of the asbestos fiber burden literature. Talc may be unevenly distributed throughout the ovarian paren-

chyma. This is supported by the discrepant counts we obtained on the one subject who had analysis of both ovaries. The lack of correspondence between polarized light and electron microscopy counts was due to measurement of different size particles.

Undocumented exposures to talc may partly explain the lack of correlation between adult histories of perineal cosmetic talc applications and ovarian burdens. Although both examination and surgical gloves in the past were dusted with talc, we cannot document this exposure. The gloves we currently use are talc free, according to the company and to our analyses. Ten of the 11 available mothers reported using talc while diapering their babies; this ubiquitous exposure may also contribute to the ovarian particle burdens.

Talc as a possible etiologic agent in the development of epithelial ovarian cancer may be related to asbestos exposure in several ways. Aside from the chemical similarities between the two, many cosmetic talcs contained significant amounts of asbestos, particularly before 1976. Although tremolite asbestos has been documented as a containment of some talc preparations, the types of asbestos detected here are more commonly associated with an environmental (chrysotile) or occupational (chrysotile and crocidolite) exposure. <sup>16</sup>

The detection of talc in all the ovaries demonstrates

<sup>\*</sup>Per gram wet tissue weight.

<sup>\*</sup>Per gram wet tissue weight.

that talc can reach the upper genital tract. However, the quantity detected in this study did not correlate well with the reported exposure. Further study is required to elucidate whether the presence of talc in ovarian tissue is pathogenic.

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# Exhibit 76

Presence of Talc in Pelvic Lymph Nodes of a Woman With Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc

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BACKGROUND: Although epidemiologic studies suggest talc use may increase ovarian cancer risk, there is no proof that talc used externally reaches the pelvis.

CASE: A 68-year-old woman with stage III ovarian papillary serous carcinoma revealed she had used talc daily for 30 years to powder her genital area. Examination of her pelvic lymph nodes under polarized light microscopy showed diffuse areas of birefringence compatible with talc, confirmed by scanning electron microscopy and X-ray spectroscopy.

CONCLUSION: This description of talc in pelvic lymph nodes of a woman with ovarian cancer and decades of exposure to talc may prompt new studies and offer new insights into the biologic basis for the consistent, but debated, association between talc use and ovarian cancer. (Obstet Gynecol 2007;110:498–501)

An epidemiologic association between the use of cosmetic talc in genital hygiene and ovarian cancer was first described in 1982, and many subsequent studies found talc use to increase risk for ovarian cancer. However, the causality of the relationship has been challenged for several reasons.

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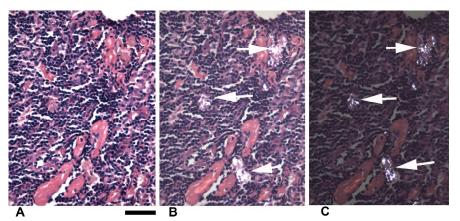
First, the association is a relatively weak one (ie, summary relative risk of approximately 1.3). Second, no clear increase in risk with duration of use has been found in most studies. Third, the ability of talc used in the genital area to enter the pelvic cavity has not been conclusively proven. At the time of pelvic surgery for ovarian cancer, pelvic lymph nodes are commonly sampled for staging purposes, but pathologic examination of the nodes is focused on the presence or absence of metastatic disease. More careful examination of pelvic lymph nodes from women with ovarian cancer may contribute to new perspectives in the debate regarding the role of talc in the causation of ovarian cancer, as illustrated by the following case.

#### **CASE**

A 68-year-old, married woman presented with abdominal swelling. A computed tomographic scan revealed a 13-cm pelvic mass, and her serum CA 125 level was more than 1,000. She was referred to the Gynecologic Oncology Service at the Brigham and Women's Hospital, where cytoreductive surgery was performed, including total abdominal hysterectomy, bilateral salpingo-oophorectomy, omentectomy, and pelvic lymph node sampling. A stage III papillary serous carcinoma with a minor clear cell component was found. Metastatic serous carcinoma was described in two of six right external iliac and obturator nodes. Postoperatively, the patient was referred for chemotherapy. She also consented to our interview about risk factors for ovarian cancer. This study is approved by the Dana Farber-Harvard Cancer Center Institutional Review Board and permits administration of general and dietary questionnaires, blood donation, and investigation of surgical specimen(s) after written informed consent. The patient's past history included three term deliveries followed by a tubal ligation. She had not smoked, used oral contraceptives, or used postmenopausal hormone therapy other than 6 months of progesterone therapy to regulate periods around the time of menopause, which occurred at age 50. There is a family history of colon cancer in a sister and maternal grandmother. At our interview, the patient stated she had used talc daily for 30 years as a body powder on the perineum and also applied it to underwear and sanitary

In searching for ideas to help clarify the association between talc use and ovarian cancer, we consulted with an expert on mesothelioma (J.G.), who pointed out that asbestos and other particulate material commonly migrates to lymph nodes.<sup>3,4</sup> We decided that a more systematic examination of pelvic lymph nodes from ovarian cancer cases might be in order, beginning with this case. In examining the patient's pelvic lymph nodes, no distinct particulates were seen under regular light microscopy, although a diffuse histocytic reaction was noted, even in a node without metastases (Fig. 1A). Under polarized light, diffuse





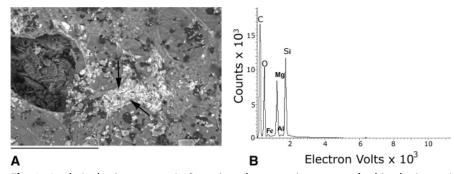
**Fig. 1.** Hematoxylin and eosin–stained section of a lymph node from the case showing morphologic findings with no polarization of the microscope light and with combinations of polarized and incident light at several different levels. **A.** Nodal morphology is illustrated and reveals no particulates seen without polarized light, but clusters of histiocytes are more prominent than usual. **B.** This panel shows the same field with polarized light plus additional light to view tissue context; birefringence is noted especially in areas of histiocyte clusters. *Arrows* are used to call attention to the birefringent particles. **C.** This shows the same field without added light, revealing the particulate nature of the birefringent material. *Arrows* highlight the particulate. Magnification bar shows 100 μm and applies to all three panels. *Cramer. Talc in Pelvic Lymph Nodes. Obstet Gynecol 2007.* 

birefringence was seen corresponding to the areas of histiocyte infiltration (Fig. 1B). Figure 1C shows the same field under polarization with no added light, revealing the particulate nature of the material, compatible with talc. Three of this patient's four nodes (not containing metastases) displayed polarizing material. Using methods described by Shelburne et al,5 we next examined lymph nodes from this patient by combined scanning electron microscopy and energy dispersive X-ray spectroscopy. Scanning electron microscopy revealed plate-like particulates in the  $5-10 \mu m$  range within the lymph node, in which energy dispersive X-ray spectroscopy showed a magnesium and silicate signature—compatible with talc (Fig. 2A,B). Dystrophic calcium deposits were also found within her nodes, probably a consequence of nodal aging. Of nodes from the next 12 patients examined, this case was strongest for

birefringence; but these nodes have not yet been subjected to scanning electron microscopy or energy dispersive X-ray spectroscopy. Figure 3 illustrates a node negative for polarization (or histiocyte reaction) from a patient with ovarian cancer who had not used talc.

#### **COMMENT**

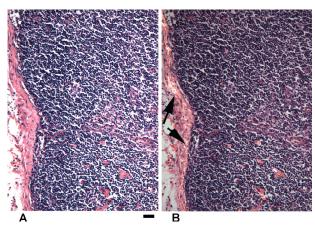
Talc is a hydrous magnesium silicate chemically similar to asbestos but structurally quite different. Asbestos has a fiber-like structure and talc a plate-like one. Because of this difference, it has been argued that the relationship between asbestos and mesothelioma should not be invoked to explain how talc might cause ovarian cancer. However, one feature of expo-



**Fig. 2.** Analytical microscopy. **A.** Scanning electron microscopy of a histologic section of the lymph node from the case shows a large collection of plate-like particulates in the 5–10  $\mu$ m range (arrows) as well as scattered individual particulates. Magnification bar shows 100  $\mu$ m. **B.** X-ray spectrum taken from the central bright area with particles reveals a Magnesium (Mg), Silicon (Si), and Oxygen (O) signature compatible with talc. A Carbon (C) signal is coming from the tissue or the underlying Carbon plancette or both.

Cramer. Talc in Pelvic Lymph Nodes. Obstet Gynecol 2007.

(3)



**Fig. 3.** Comparative node section illustrated from a woman reporting no talc use. **A.** Hematoxylin and eosin stained section showing fewer macrophages than seen in the node in Figure 1A. Magnification bar shows 100  $\mu$ m. **B.** Polarized light examination of the same area of the node showing only some birefringence in the node capsule (*arrows*) compatible with collagen.

Cramer. Talc in Pelvic Lymph Nodes. Obstet Gynecol 2007.

sure that the minerals do have in common is nodal dissemination. Migration and entrapment in lymph nodes is observed in human asbestos exposure and correlates with the asbestos burden.<sup>3</sup> Talc has also been described in pulmonary lymph nodes of talc miners.<sup>4</sup> However, a MEDLINE search of (all language) publications between January 1950 and February 2007 using the search terms, "talc," "birefringence," "histiocytosis," "lymph nodes," and "ovarian neoplasms," revealed no reports of talc in lymph nodes of ovarian cancer patients.

In one of the few studies in women to evaluate the potential for talc to migrate into the pelvis, Heller et al studied normal ovaries from women having oophorectomy for benign disease.6 The protocol involved a multistep process of tissue rehydration, blotting, drying, digestion, rehydration, centrifugation, and multiple washes. After this process, polarizing bodies were found in all ovarian specimens examined by light microscopy. By electron microscopy, tissues from 5 of 12 women who regularly used talc and 6 of 12 who had not were found to have particles consistent with talc. The investigators concluded that talc can be found in ovaries but that this does not correlate with genital talc use. Contamination that might have been introduced during extensive processing is a potential weakness of this study.

In this case report, we describe examination of pelvic lymph nodes from a woman with ovarian cancer who had been a long-term talc user. Particles compatible with talc were clearly visible under polarized light in regular hematoxylin and eosin-stained sections from her pelvic nodes, which were then shown by scanning electron microscopy and energy dispersive X-ray spectroscopy to be talc. Thus, as opposed to the aforementioned study, we focused on pelvic lymph nodes rather than ovaries; and talc was shown to be present in macrophages within the actual tissue, ruling out contamination during processing.

In reporting this case, we are not proposing that pelvic lymph nodes from women with ovarian cancer must now be subjected to electron microscopy. However, pathologists may wish to examine pelvic lymph nodes with evidence of histiocytic infiltrates by polarized light microscopy. Clear evidence of polarization may be reported so that clinicians can obtain information about potential talc exposure, if this information has not already been collected. Also we are not claiming that a causal relationship between ovarian cancer and talc use is proven for this case or in general. Because case reports cannot establish causality, we have begun a more extensive study of nodes with two purposes. First it is necessary to establish in a quantitative manner the likelihood of finding talc in lymph nodes of women with ovarian cancer and correlate this by whether they did or did not use talc. Second, studies of immune markers in nodes may help make the case for a causal connection.

What we do hope this case report accomplishes is to infuse a fresh perspective on the talc and ovarian cancer association. Previous biologic arguments linking talc and ovarian cancer have been based upon: similarities between talc and asbestos, the ability of talc to reach the ovaries through the open female tract, and induction of a mesothelioma-like cancer from the ovarian epithelium. Our new perspective would not depend upon structural similarities between talc and asbestos. The adverse effects of talc may relate to its ability to induce an inflammatory reaction, a well-established property of talc, independent of any similarity to asbestos.7 Also, we don't believe that talc needs to reach the ovaries to affect ovarian cancer risk; rather, the harmful effects of talc may involve inflammatory reactions in the lower genital tract, including the upper vagina, cervix, and endometrium. These tissues express the surface glycoprotein human mucin 1, MUC1, whose function is to protect cells from environmental stressors. It is likely that chronic talc exposure is one factor that upregulates MUC1 expression. Human mucin 1 is related to CA 125 (MUC16), and like CA 125 is overexpressed in ovarian cancer. It is known that women with ovarian cancer who have anti-MUC1 antibodies survive longer, leading us to propose that many risk factors for ovarian cancer may be explained by their ability to raise or lower MUC1 immunity. Looking at predictors of anti-MUC1 antibodies, talc use was a factor that lowered anti-MUC1 antibodies. Thus, rather than a direct carcinogenic effect on ovarian epithelium, immune dysregulation involving MUC1 may be induced by chronic talc use that may lower protective immunity. Furthermore, sequestration of talc in nodes may affect antigen processing and be another important element in the postulated immune dysregulation.

In conclusion, this description of talc in pelvic lymph nodes of a long-term talc user with ovarian cancer may begin to reshape understanding about the relationship between talc and ovarian cancer and shed new light on whether talc used externally in the genital area is capable of migrating into the pelvis.

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## Postpartum Sudden Death From Pulmonary Hypertension in the Setting of Portal Hypertension

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**BACKGROUND:** Pulmonary arterial hypertension carries a high maternal mortality rate in the peripartum period. Pulmonary hypertension may arise as a complication of portal hypertension with poor patient survival.

CASE: A young primigravida with chronic autoimmune hepatitis and portal hypertension presented at 26 4/7 weeks of gestation with contractions and bleeding. Within 48 hours, an 892-g female fetus was delivered vaginally without complications. On postpartum day 2, the mother was found on the floor by her bed. Although

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initially responsive, within minutes she was unresponsive and resuscitation was unsuccessful. Postmortem examination showed cirrhosis and plexogenic pulmonary arteriopathy.

CONCLUSION: Increased awareness of pulmonary hypertension as a complication of portal hypertension and a high index of clinical suspicion are necessary to diagnose pregnant women with this condition and provide appropriate prenatal counseling and peripartum intervention.

(Obstet Gynecol 2007;110:501-3)

Pulmonary hypertension is an under-recognized complication of portal hypertension. We present an individual with known autoimmune hepatitis with cirrhosis and portal hypertension where underlying pulmonary hypertension was identified after her postpartum sudden death. Pulmonary hypertension may present in a subtle manner, but is important to appreciate in this high-risk obstetric patient population.

#### **CASE**

A young primigravida with a 10-year history of autoimmune hepatitis with chronic thrombocytopenia presented to the hospital at 26 4/7 weeks of gestation with contractions and bleeding. Before her pregnancy, she was a noncompliant transplantation candidate not using birth control. Prenatal care had been initiated at 6 weeks of



# Exhibit 77



## **Ultrastructural Pathology**

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## Correlative polarizing light and scanning electron microscopy for the assessment of talc in pelvic region lymph nodes

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#### **ABSTRACT**

Perineal talc use is associated with ovarian carcinoma in many case-control studies. Such talc may migrate to pelvic organs and regional lymph nodes, with both clinical and legal significance. Our goal was to differentiate talc in pelvic lymph nodes due to exposure, versus contamination with talc in the laboratory. We studied 22 lymph nodes from ovarian tumor patients, some of which had documented talc exposure, to quantify talc using digestion of tissue taken from paraffin blocks and scanning electron microscopy/energy dispersive X-ray analysis (SEM/EDX). Talc particles correlated significantly with surface contamination assessments using polarized light microscopy. After adjusting for surface contamination, talc burdens in nodes correlated strongly with perineal talc use. In a separate group of lymph nodes, birefringent particles within the same plane of focus as the tissues in histological sections were highly correlated with talc particles within the tissue by in situ SEM/EDX (r = 0.80; p < 0.0001). We conclude that since talc can be a surface contaminant from tissue collection/preparation, digestion measurements may be influenced by contamination. Instead, because they preserve anatomic landmarks and permit identification of particles in cells and tissues, polarized light microscopy and in situ SEM/EDX are recommended to assess talc in lymph nodes.

#### **ARTICLE HISTORY**

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#### **KEYWORDS/PHRASES**

talc; scanning electron microscopy; carcinoma; birefringence

#### Introduction

In diseases related to foreign particulate exposure, accurate quantification of foreign material in tissue is important to document exposure and to correlate with disease occurrence or severity related to that tissue.<sup>1</sup> The issue is perhaps best appreciated for asbestos and pulmonary mesothelioma and fibrosis.<sup>2</sup> The most comprehensive quantification is obtained by digestion of a tissue sample, which uses much larger amounts of tissue that can be assessed in a histologic tissue section. The procedure can be used to identify and quantify individual fibers by transmission electron microscopy (TEM) or scanning electron microscopy (SEM) and characterize them by energy dispersive x-ray analysis (EDX) to verify that their elemental signatures are compatible with a specific type of

asbestos or other foreign material exposure<sup>3</sup> Application of TEM and/or SEM and EDX to tissue sections cut from paraffin blocks also provides quantification when the concentration of particles in tissue is sufficiently high.<sup>4,5</sup> This procedure may also show where the foreign material resides within a tissue section, such as exogenous particles localizing in macrophages within lymph nodes.<sup>6</sup> An estimate of foreign particulate exposure may also be obtained by studying histologic tissue sections under polarized light microscopy, which highlights birefringent material and its size and shape. 7,8 Besides the use of these methods in scientific studies to characterize exposures and disease, these techniques have also been used in medicolegal contexts related to claims of injury from various exposures, including asbestos.<sup>1</sup>



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One exposure of great current medical, public health, and medicolegal importance is the association of ovarian cancers with the use of talc cosmetic products in the genital area. Data related to this association come from epidemiologic studies which identified a clear excess of women with ovarian malignancy who had used talc in their genital area prior to developing cancer, compared to control women. 9-13 The International Agency for Research on Cancer has declared the use of talc (not containing asbestos) in the genital area as possibly carcinogenic (Class 2B) (IARC monograph, 2010).<sup>14</sup> The most recent summary of the epidemiologic data in 2018 found that genital talc use may increase the risk for ovarian carcinoma by about 30%. 15 Although the origin of the hypothesis about talc and ovarian cancer came, in part, from description of talc in ovarian tissue, 16 demonstration that talc is present in the ovarian tissue or the genital tract from women with ovarian cancer has not been a component of the epidemiologic studies, and published data regarding talc in women's pelvic organs is very limited. A study by Heller et al.17 was done with digestion techniques followed by TEM on ovaries from 24 women having hysterectomy/oophorectomy for reasons other than ovarian malignancy. This study found talc in approximately half the samples, with no obvious correlation with genital talc use history, thereby suggesting to the authors that talc exposure may be relatively ubiquitous across the population. A subset of authors from the present study have previously described a case report<sup>6</sup> in which a woman with serous carcinoma of the ovary, and a history of talc usage in her genital area, was demonstrated to have talc in three of four examined pelvic lymph nodes.

In the study reported here, we assessed talc in a sizable set of lymph nodes of the pelvic region, representing multiple patients. Thus, we expanded on the lymph node analysis in the previous case report<sup>6</sup> as well as the study of non-malignant ovaries by Heller et al.<sup>17</sup> and we examined nodes in 22 patients with various types of ovarian tumors. We included the additional step of an independent polarized light microscopy study on the histological sections for each case; this procedure assessed the quantity and location of birefringent particles in relationship to tissue landmarks.

By digesting the lymph node samples, assessing the presence of talc by SEM/EDX, and comparing that data to the findings by light microscopy, we assessed tissue surface contamination as a factor explaining the high talc burden in some cases, as opposed to talc that migrated to the nodes from perineal exposure. We also endeavored, by studying a separate group of lymph node cases, to show that polarized light microscopy is a useful adjunct to *in situ* SEM/EDX, since both preserve anatomic landmarks and can serve as indicators of talc whose source is not due to contamination.

#### **Materials and methods**

Twenty-two women with ovarian tumors who had received their care in 2004 and 2005 at the Brigham and Women's Hospital (BWH), and who had participated in larger epidemiologic studies of ovarian cancer in Eastern Massachusetts and New Hampshire, were selected for the study. Women in this series were selected consecutively on the basis of meeting eligibility criteria and not on the basis of whether they had used talc. To be eligible, cases must have had lymph nodes removed from the pelvic region as part of their surgery. Cases were ineligible if the only nodes available contained metastatic disease or if there was only one unaffected node available. Though most of the cases were malignant ovarian neoplasms, two cases (one a borderline tumor and the second a granulosa cell tumor) were included because the study's objective was focused on the quantification of talc in tissue and understanding contamination vs. exposure related findings. Relevant clinical data were available both from the medical record and questionnaires completed by the women that included information on the use of talc in the genital area or as a body powder. The study was approved by the BWH Institutional Review Board and the informed consent signed by the women included permission to study material removed at the time of surgery. This group of women had both digestion studies and light microscopic studies of their lymph nodes. For our purposes, nodes of interest included inguinal, iliac, and paraaortic, and potentially any node of the pelvic region used for sampling and/or staging in ovarian surgical oncology. In some cases, the designation "pelvic lymph node" with laterality, but without further anatomic specification, was provided with a sample.

Talc is readily visible under polarizing light microscopy, where it may be found as both plates and fibrous forms, and where the particles or fibers are brightly birefringent and often in the size range 1–10 µm. Identification of talc by electron microscopy and energy-dispersive X-ray analysis (EDX), includes the plate-like particulate or fiber-like structure and a spectrum showing magnesium and silicon peaks within 5% of the theoretical atomic ratio of 0.75 and atomic weight percent ratio of 0.649.

For each patient case, we ascertained that an acceptable representative hematoxylin-eosin (H&E)-stained slide was available for the block prior to subsequent steps. Tissue was totally cut from the paraffin block with a cleaned scalpel, heat deparaffinized, and then multiple extractions were done with xylene to remove all residual paraffin. The tissue was weighed, then added to glass centrifuge tubes, and sodium hypochlorite solution was added for digestion over a 24-48 hr period. When digestion was complete, samples were centrifuged and the sediment resuspended in filtered distilled water and vortexed until no sediment was visible. The tubes were centrifuged again and the supernatant aspirated. Sediments were resuspended in 25% ethanol, mixed by vortexing and filtered through a 13 mm, 0.2 µm Millipore filter. Tubes were washed twice with 25% ethanol and filtered. Filters were dried in a desiccator and were mounted on a carbon planchette.

Samples were analyzed in a scanning electron microscope (Leo 1460VP) equipped with an EDX spectrometer (Oxford instruments with Inca software) or an Hitachi SU6600 field emission scanning electron microscope with Oxford EDX (Xmax 50SDD EDX detector) and Oxford instrumentation software (Aztec 3.3). At 2000x magnification, 200 particles or 100 random fields were analyzed for each case, whichever came first. Using various parameters, including the number of talc particles identified by their chemical composition, the area of each microscopic field times the number of fields examined, and the overall filter area, an estimate for the total number of talc particles in the specimen was calculated.

Because fat, fibrous tissue, and lymph node contributed to the weight of the material used for digestion and because there were differences in birefringent particle distribution patterns of the tissue surface, fat and fibrous tissue, and lymph node, a more accurate approach was needed by which we could estimate the contributions of the separate locations. Tissues on all slides were digitized. Using NIH Image J analysis software (an open source image processing program, www.imagej.com), the total areas (cm<sup>2</sup>) of the tissue on the slides for each case were calculated, as well as the respective components of lymph node and fibroadipose (soft) tissue, with the sum of these areas adding up to the total tissue area. These figures were then multiplied by 0.25 cm (a typical thickness for tissue in paraffin cassettes from which the digested tissues were derived) to obtain total specimen volumes for the total tissue, and for the lymph node and soft tissue components. The total number of talc particles identified in the digestate by SEM was then divided by the total tissue volume to obtain the number of talc particles per unit volume (cm<sup>3</sup>).

H&E slides of intact lymph node tissue corresponding to each digested paraffin sample were analyzed with an Olympus BH-2 light microscope equipped with polarizing filter capabilities (analyzer and rotating polarizer with specimen slide in between). Each slide was scanned systematically and completely at 200x magnification under polarized light. Slides typically contained one to several lymph node profiles with adherent fibroadipose tissue. Birefringent particles visually consistent with talc (typically 1-10 µm with birefringence) were counted that were located within the lymph node parenchyma and sinuses, and a separate count was made of particles in fibroadipose (soft) tissue, i.e. not within the lymph nodes proper. The counts of these two components were added to get the total count. Particles within fibroadipose tissue were counted only if they were at least one 400x (high-power) field away from the surface, so that obvious surface contamination was not included in the counts. The birefringent particles present within lymph nodes were taken to indicate clinically significant talc that migrated there through the lymphatic system. Birefringent particles on the physical surface of the tissues were not counted for these analyses but instead assessed as described below.

Using the aforementioned image analysis data which provided the areas (cm²) for the total tissue on the slide as well as the lymph node and soft tissue components, for each slide, the respective tissue volumes were calculated by multiplying the areas by 4  $\mu$ m (4×10<sup>-4</sup> cm), a standard tissue section thickness on glass slides. The number of birefringent particles per unit volume were then calculated (through simple division) for each tissue component and for the overall tissue. This meant that the volume correction factor between tissue blocks and tissue slides was approximately 625 (0.25 cm thickness of tissue in blocks vs. 4  $\mu$ m thickness of slides).

Additionally, for each of the 22 cases, a semiquantitative visual estimate of surface contamination was made. This was done by observing the quantity and pattern of all polarizable material (typically birefringent particles of 1-10 μm, plus larger material such as paper, organic fibers, and other debris) that were present along the specimen edge and/or within one 400x (high power microscopic field) width from it. The objective here was to measure the degree to which the specimen surfaces might have been contaminated by physical manipulation during the acquisition and handling steps of the specimen in the Pathology department. Our estimate scores ranged from 0 to 3 and the criteria for the scoring was as follows (see Figure 1): 0, no polarizable material along surface; 1, occasional foreign particulates, rarely forming small clusters; 2, moderate numbers of surface particulates, forming occasional clusters or surface patches more numerous than in score 1; 3, frequent patches of particulates along with confluent stretches of contamination along the surface. Typically, such contamination was seen along the fibroadipose tissue surface with the nodal tissue interior to that. The contamination consisted typically of a mix of larger debris consistent with paper, along with smaller birefringent particulates similar to those seen and described in tissue sections (Figure 1). All contamination scores were done by a pathologist (JJG) in a blinded fashion (SEM and clinical data were unavailable at the time of scoring). A randomly chosen subset of the same cases was independently scored by a second pathologist (SM), also in a blinded fashion, to confirm successfully that the review

standards agreed, and thus the scoring standards were being applied consistently.

Subsequent statistical analysis for the 22 cases was handled as follows: Talc counts were log transformed to create normal distributions. Spearman correlations were calculated to assess the relationship between potential contamination on the talc counts and each continuous variable, and partial correlations were used to examine the relationships between talc counts, adjusted for contamination. Linear regression was used to calculate crude and contamination-adjusted talc/total volume geometric means and 95% confidence intervals.

Also, as part of this report, we studied a second group of 19 lymph node specimens from 10 ovarian carcinoma cases. The 10 cases were consults of authors JJG and WW, which were de-identified, i.e. reported here without any patient identifiers, including the 18 recognized HIPAA identifiers. 18 All 19 tissue specimens had histologic slides and corresponding paraffin blocks available. In this component of the study, we assessed the relationship of the numbers of birefringent particles in the lymph node parenchyma in histological sections, and talc particles found by in situ SEM/EDX at deeper levels in the tissue blocks corresponding to those sections. Digestion was not performed on these cases; nor was information available on their talc exposure. Birefringent particles in the lymph nodes were exhaustively quantified by light microscopy as previously described (particles counted in respective lymph node and soft tissue components, added to a total count for each slide). The histologic slides typically contained from one to several lymph node profiles, each with adherent fibroadipose tissue. Counting was done without regard to the number of profiles; i.e. an aggregate count was obtained across all lymph node tissue on a slide.

The tissue blocks were handled with a procedure for *in situ* SEM/EDX distinct from the tissue digestion and filter analysis by SEM described in the previous component of the study. This *in situ* procedure was first described by Thakral and Abraham<sup>4</sup> for assessment of particulate materials in paraffin-embedded tissue. In the study reported here, the blocks were handled with particle-free gloves on pre-cleaned surfaces and sectioned removing ~30 micrometers of tissue

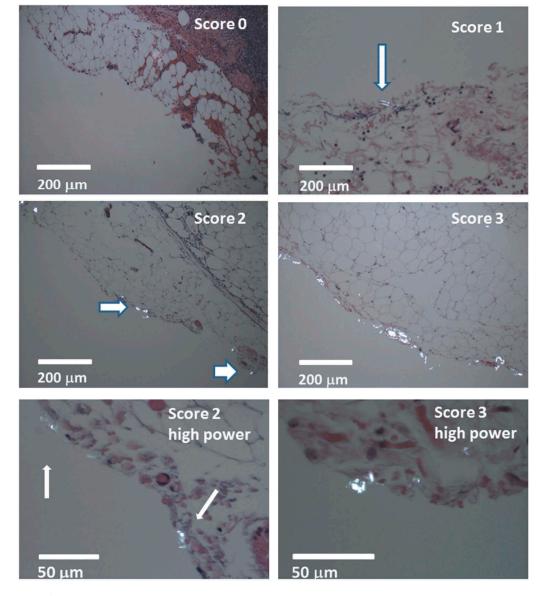


Figure 1. Tissue surface contamination score semi-quantitative grading. As shown especially in the two high-power images at bottom, the contamination material consisted typically of larger debris consistent with paper, along with smaller birefringent particulates. Surface contamination was typically found along the fibroadipose tissue surface, with lymph node tissue located underneath. Grading scheme is as follows: Score 0: no polarizable material along surface. Score 1: occasional birefringent particulates (arrows), rarely forming small clusters. Score 2: moderate numbers of surface birefringent particulates (arrows), forming occasional clusters or surface patches more numerous than in score 1. Score 3: frequent patches of particulates along with confluent stretches of contamination along the surface. (All images under polarizing light microscopy, H&E staining, all 100x except 400x [original magnification] in the bottom two images which respectively show score 2 and 3).

and paraffin using a rotary microtome with a new, clean stainless-steel blade. This sectioning was intended to remove any surface contamination from previous storage and handling. After the fresh surface was exposed, the block surfaces were washed in distilled, deionized water for 30 seconds to remove soluble surface materials such as sodium chloride and sodium phosphates used in processing for histology. The blocks were

mounted for SEM examination and always kept in closed containers to limit any lab contamination. These tissue surfaces were studied with a Hitachi SU6600 field emission SEM with an Oxford EDX with Aztec version 2.0 to 3.3 software, and EDX detector model X-Max 50 SDD. The backscatter mode of the microscope highlighted mineral particles within the tissues. Areas of the tissue at the sectioned block surface were examined at relatively low magnification 200-500x, and when particles were seen, they were then examined at higher magnification for morphological characteristics and to carry out spectral analysis on each particle found. Electron beam penetration depth under the conditions used was estimated to be 2.5 μm, with an analysis range of 0.5–2.5 μm. Of note, under in situ SEM the interior tissue and exterior tissue surfaces were readily distinguishable; this distinction was important for our study. In particular, as subsequent discussion will show, it was important to avoid analyzing surface particulates and instead analyze those inside the tissue. Having a scanned photocopy of the light microscopic slide and the block surface available for reference when performing SEM/EDX helped in navigating the anatomic landmarks, including surface vs. tissue interior location. We subsequently carried out an auxiliary part of this study, in which surface contamination of tissue slides was assessed using two of the cases that had this finding. The surface particles were assessed by in situ SEM/EDX to determine the identity (i.e. chemical composition) of the surface contamination.

For this second part of the study, linear regression analyses, with the generation of a coefficient of determination (r) goodness-of-fit value, were done between three statistical pairings: total birefringent particles by light microscopy vs. in situ SEM/EDX talc counts, lymph node birefringent particles vs. in situ SEM/EDX talc count, and fibroadipose tissue birefringent particles vs. in situ SEM/EDX talc counts. Our hypothesis was that the first two pairings would be correlated but the last one would not. The inclusion of multiple specimens from some of the patients meant that the 19 data points (specimens) were not truly independent of each other from the perspective of the population. However, from a statistical point of view, this was justified because, in this phase of our study, the purpose was an evaluation of methods and data related to the samples themselves, and not the population from which the samples were drawn.

#### Results

#### **Digestion study**

Table 1 shows characteristics of the 22 subjects enrolled in the BWH node digestion study, arrayed

(least to greatest) by the amount of talc (by digestion) per cm<sup>3</sup> tissue volume. Fourteen (64%) of the women had invasive serous ovarian carcinoma of the ovary, which in one case was mixed with endometrioid carcinoma. Nineteen of the 22 nodes (86%) were external iliac, with 11/19 (58%) from the right side. The age range of the women was 38-73 with a median of 56; 10 (45%) had used talc in their genital area and 16 (73%) had used it as a body powder. There was considerable variation in total talc counts seen after digestion of the nodes. There was also considerable variation in birefringent particle counts in the nodal components, as well as corresponding counts per cm<sup>3</sup> tissue volume (see column totals where pertinent). The number and proportion of nodes with 0, 1, 2, and 3 surface contamination scores were: 4(18%), 7(32%), 7(32%), and 4 (18%).

Of note, cases 4, 9, and 13 had no clinical exposure history, and yet all had high contamination scores (either 2 or 3) and corresponding moderate to high talc counts per cm³ tissue volume, thus highlighting a role for contamination in their digestion results. In contrast, cases 10 and 18 had clinical **exposure**, **but** zero contamination scores (i.e. no visible surface contamination); they also had significant talc counts per cm³ tissue volume, indicating that in the absence of surface contamination, clinical exposure yields significant talc counts using digestion. Case 18 can also be contrasted with cases 19–22, which had the four highest talc counts per cm³ tissue volume (Table 1), and all of which had high levels of surface contamination.

Table 2 shows Pearson and partial correlations among the various quantitative measurements related to talc and birefringent particles. The degree of surface contamination (0–3 score) as it correlates with other measures of talc and birefringent particles within the node is shown in the right-most column. The surface contamination score was significantly correlated with: the total talc particle count by digestion (r = 0.43, p = 0.05); with birefringent particle counts by light microscopy in the soft tissue (fibroadipose) component (r = 0.53, p = 0.01); with total talc per cm<sup>3</sup> tissue volume by SEM/EDX (r = 0.57, p = 0.006); and with birefringent particle counts in fibroadipose tissue per cm $^3$  fibroadipose volume (r = 0.51, p = 0.01). The remainder of correlations and p values in Table 2 represent those for partial correlations

Table 1. Clinical data and talc digestion and light microscopic data among the first patient group (BWH cases).

		L																										
	Surface	contamination	-	_	0	2	0	_	_	_	2	0	2	2	m	7	2	-		-	0	Ж	2	m	Э			
nponent cm³)		Fat	17,250	3,812	23,271	20,187	17,406	9,937	18,937	18,375	26,715	41,375	291,687	908,750	125,125	84,437	33,937	101,875		49,437	3,000	285,625	12,437	735,294	000′6		24,993	
efringence per compon volume (particles/ cm³)		Node	6,375	3,661	52,301	4,960	66,286	3,687	3,187	0	35,014	15,125	6,812	269,125	56,562	12,937	151,500	45,437		228,687	>616,365	71,875	16,875	32,051	>220,062		33,533	
Birefringence per component volume (particles/ cm³)		Total	11,000	3,737	34,552	11,187	45,146	5,387	7,912	11,687	28,103	18,500	46,750	402,437	114,812	37,062	53,125	80,812		176,000		215,000	15,312	246,875	>147,500		41,104	
		Fat	2500	625	4375	3125	2500	625	3125	1250	11875	1,250	4,375	2,000	5,625	6,250	14,375	9,375		2,500	^		1,250		1,250 >		3,125	
gence cou		Node	1250	625	6250	1250	12500	625	1250	0	3125	3,125	625	5,625	1,250		_	2,500		28,125	>125,000	_		_	>62,500		2,188	
Total birefringence counts††		Total	3750	1250	10625	4375	15000	1250	4375	1250	15000	4,375	2,000	10,625	16,875	8,125	26,875	11,875					4,375	13,750	>62,500		10,625	
	Talc/cm <sup>3</sup> of tissue	volume	2,475	4,800	6,705	10,540	11,942	14,500	16,000	23,562	35,823	85,600	97,100	107,300	115,030	138,500	144,800	145,600		194,100	208,200		325,200	1,518,589	1,881,500		102,200	
	Total	talc †	844	1608	2065	4290	3965	3378	8920	2533	19,094	20,267	10,390	2,834	16,057	30,330	73,267	21,409		33,778	67,557	12,661	92,891	85,041	797,171		14,359	
nse		Body	Yes	Yes	Yes	No	Yes	N <sub>o</sub>	N <sub>o</sub>	Yes	N <sub>o</sub>	Yes	N <sub>o</sub>	Yes	N <sub>o</sub>	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes			
Talc use		Genital	N S	No No	No No	No	No No	Yes	No No	Yes	9	Yes	٩	Yes	٩	Yes	Yes	٩		Yes	Yes	No No	Yes	٩	Yes			
		Age	09	53	69	38	54	20	46	49	27	49	51	51	89	73	28	09		62	53	69	99	21	69		26	
ıme (cm³)		Fat	0.146 (43%)	0.164 (49%)	0.188 (61%)	0.155 (38%)	0.143 (43%)	0.063 (27%)	0.165 (30%)	0.069 (64%)	0.444 (83%)	0.030 (13%)	0.015 (14%)	0.006 (21%)	0.125 (85%)	0.074 (34%)	0.423 (84%)	0.092 (63%)		0.051 (29%)	0.121 (37%)	0.035 (67%)	0.101 (35%)	0.017 (30%)	0.139 (33%)		0.111	
Component volume (cm³)		Node	0.195 (57%)	0.171 (51%)	0.119 (39%)	0.252 (62%)	0.189 (57%)	0.169 (73%)	0.392 (70%)	0.039 (36%)	0.089 (17%)	0.206 (87%)	0.092 (86%)	0.021 (79%)	0.022 (15%)	0.145 (66%)	0.083 (16%)	0.055 (37%)		0.123 (71%)		0.017 (33%)		0.039 (70%)	0.284 (67%)		0.262 0.134	
ပိ		Total	0.341	0.334	0.308	0.407	0.332	0.232	0.557	0.107	0.533	0.237	0.107	0.026	0.147	0.219	0.506	0.147		0.174	0.323	0.052	0.286	0.056	0.424		0.262	
		Node*	REI	Ъ	三	E	REI	REI	REI	回	REI	REI	REI	RP	回	REI	REI	REI		回	回	9	9	REI	RPA			
	Tumor	histology	Endometrioid	Serous invasive	Serous invasive	Serous invasive	Clear cell	Serous invasive	Endometrioid	Serous invasive	Endometrioid	Granulosa cell	Serous invasive	Serous invasive	Serous invasive	Serous invasive	Endometrioid	Serous	borderline	Serous invasive	Serous invasive	Serous invasive	Serous invasive	Endometrioid	Serous/	endometrioid		
	Case	number	-	7	3	4	2	9	7	8	6	10	1	12	13	14	15	16		17	18	19	20	21	22		Median	

\*Location of Node: LEI = Left external iliac; REI = Right external iliac; RPA = Right paraaortic; LP = Left pelvic; RP = Right pelvic

+Total number of talc particles by digestion (calculated)
++Total birefringence counts = particles in field x 625 (see Materials and Methods)
Node refers to lymph node parenchyma areas as measured by Image J software and studied by light microscopy (see Materials and Methods).
Fat refers to fibroadipose soft tissue areas as measured by Image J software and studied by light microscopy

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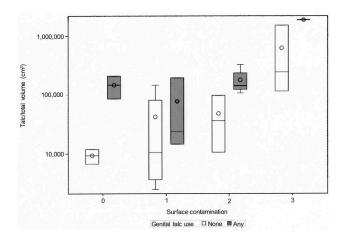
							Birefringent	irefringent particle counts per cm²	ts per cm
			Total bire	Total birefringent particle counts	counts			volume	
	Surface contamination	Total talc by digestion	Total	Node	Fat	Talc/total volume	Total	Node	Fat
Variable*	r (p)	r (p)	r (p)	r (p)	r (p)	r (p)	r (p)	r (p)	r (p)
Total talc by digestion	0.43 (0.05)								
Total birefringent particle counts	0.15 (0.51)	0.67 (0.001)							
Total birefringent particle counts, node	-0.07 (0.77)	0.59 (0.005)	0.81 (<.0001)						
Total birefringent particle counts, fat	0.53 (0.01)	-0.13 (0.58)	0.25 (0.26)	0.07 (0.76)					
Talc/cm³ volume	0.57 (0.006)	0.87 (<.0001)	0.63 (0.002)	0.47 (0.03)	-0.06 (0.78)				
Birefringent particles per cm <sup>3</sup> total volume	0.33 (0.13)	0.42 (0.06)	0.82 (<.0001)	0.56 (0.008)	0.3 (0.19)	0.68 (0.0007)			
Birefringence per cm <sup>3</sup> node volume	0.07 (0.77)	0.51 (0.02)	0.90 (<.0001)	0.88 (<.0001)	0.18 (0.45)	0.64 (0.003)	0.87 (<.0001)		
Birefringence per cm³ fat volume	0.51 (0.01)	-0.24 (0.30)	0.003 (0.99)	-0.1 (0.68)	0.61 (0.003)	0.16 (0.48)	0.45 (0.04)	0.13 (0.58)	
Age	0.28 (0.20)	0.26 (0.26)	0.35 (0.12)	0.32 (0.15)	0.16 (0.49)	0.22 (0.33)	0.26 (0.25)	0.36 (0.12)	0.36 (0.12) -0.07 (0.75)
Node = lymph node tissue									

Fat = fibroadipose tissue

unexpectedly, total counts always strongly correlated with counts per cm<sup>3</sup> of relevant tissues: e.g. total talc with total talc per cm $^3$  tissue volume (r = 0.87, p = 0.001); total birefringent particle counts in lymph node tissue with birefringent counts per cm<sup>3</sup> lymph node tissue (r = 0.88, p = 0.0001); and birefringent particle counts in fibroadipose tissue with birefringence counts per cm<sup>3</sup> fibroadipose volume (r = 0.61, p = 0.003). Talc counts per cm<sup>3</sup> tissue volume correlated with: birefringent particles per cm<sup>3</sup> tissue volume (r = 0.68, p = 0.007), and lymph node birefringent particles per cm<sup>3</sup> lymph node tissue (r = 0.64, p = 0.003), but not with fibroadipose birefringent particles per cm<sup>3</sup> fibroadipose tissue. Total birefringent particles per cm<sup>3</sup> tissue volume correlated best with lymph node birefringent particles per cm<sup>3</sup> lymph node tissue (r = 0.89, p = 0.001). Birefringent particle counts per cm<sup>3</sup> lymph node tissue were not correlated with fibroadipose birefringent particle counts per cm<sup>3</sup> fibroadipose volume. Age was not significantly correlated with any measure of nodal contamination.

adjusted for the level of surface contamination. Not

Figure 2 and Table 3 illustrates the potential effect of surface contamination on the interpretation of the relationship between total talc (by digestion) per cm<sup>3</sup> tissue volume. Figure 2 illustrates that for any level of surface contamination, those who used talc in the genital area had a higher amount of talc than those who had not used talc genitally. Table 3 quantifies



**Figure 2.** Talc/total volume for genital talc users and non-users by surface contamination This figure shows surface contamination scores (x axis) plotted against talc per tissue volume (y-axis, logarithmic scale), showing that for any level of surface contamination, those who used talc in the genital area had a higher amount of talc than those who had not used talc genitally.

Table 3. Geometric mean talc/total volume by genital talc use.

	No genital talc use $(n = 12)$ Geometric		
	mean	Any genital talc use $(n = 10)$ Geometric mean	
Talc/total volume	(95% CI)	(95% CI)	p-value
Crude	35,049 (13,637, 90,079)	131,584 (46,787, 370,070)	0.08
Adjusted for surface contamination	29,926 (15,546, 57,605)	159,056 (77,491, 326,475)	0.004

this effect more precisely and indicates that, overall, the genital talc user had higher talc counts per volume of tissue than those who had not used talc, but the association was of borderline significance. After adjustment for level of surface contamination, the association became significant (p = 0.004) with the level of talc in nodal tissue at least five times higher in those who used talc genitally compared to those who had not.

Figure 3 shows correlative polarizing light microscopy, SEM, and EDX from case 18 in the digestate study (Table 1). Going clockwise from upper left, panel A shows polarized light microscopy (H&E, 200x), showing numerous birefringent particles (general size range 1 to 5 μm) within the macrophages of a left external iliac lymph node. This case was near the upper end of the range of particle abundances we observed. Panel B shows examples of two particles (labeled 1103 and 1104), identified by SEM on the digestate filter, each <5 µm diameter. Panel C shows the spectrum for particle 1103, with an Mg-Si atomic weight ratio of 0.6495, characteristic of talc. The other particle in **B**, 1104, had an Mg-Si ratio within 5% of the theoretical talc value (0.649).

#### In situ SEM study

Table 4 shows data for the second part of the study (19 lymph node specimens from 10 patients). The leftmost two columns (case number and block letter) are

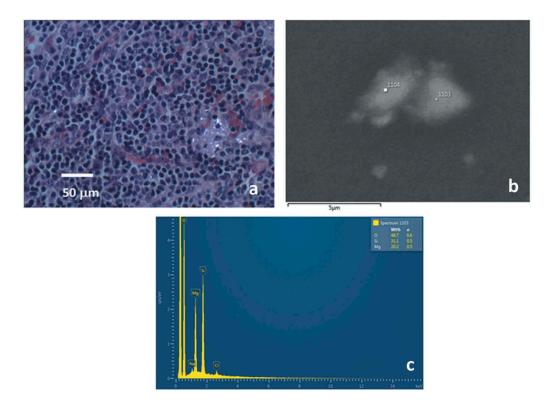


Figure 3. Correlative polarizing light microscopy, SEM, and EDX from case 18 in the digestate study (Table 1). Clockwise from upper left: a, Polarizing light microscopy, H&E, 200x, showing numerous birefringent particles (general size range 1 to 5 μm) within the macrophages of a left eternal iliac lymph node. b, Two particles (labeled 1103 and 1104), identified by SEM on the digestate filter, each <5 µm diameter. c, Spectrum for particle 1103, The Mg-Si atomic weight ratio is 0.6495, characteristic of talc. The other particle in **b**, 1104, had an Mg-Si atomic weight ratio within 5% of the theoretical talc value (0.649).

**Table 4.** Correlation between light microscopic birefringent particulates and in situ SEM analysis for talc particles.

			Birefringent	Total	Number of talc
		Birefringent	particles in	birefringent	particles
		particles in	surrounding	particles in	in the
		lymph node	fibroadipose	slide	block by
Case	Slide	tissue (total	tissue (total	(columns	in situ
number	letter	per slide)	per slide)	C + D)	SEM
1	Α	3	5	8	0
	В	55	7	62	5
2	Α	5	2	7	9
3	Α	2	0	2	0
	В	0	0	0	0
4	Α	19	9	28	31
	В	3	1	4	5
5	Α	>500	3	>500	65
6	Α	6	4	10	0
	В	8	3	11	0
	C	16	4	20	0
7	Α	7	3	10	1
	В	1	0	1	0
8	Α	>100	3	>100	18
	В	>200	2	>200	43
	C	>100	5	>100	35
	D	>100	7	>100	24
9	Α	8	6	14	1
10	Α	15	>50	>50	12

In this part of the study, 19 pelvic lymph node slides on 10 ovarian carcinoma patients (with each patient having from one to four node specimens), showed the relationship of the numbers of birefringent particles (by light microscopy) within histological sections (separately categorized in lymph node and fibroadipose tissue components), and talc particles found by SEM/EDX at deeper levels in the tissue blocks corresponding to those sections (right-hand column). In case 9C, the vast majority of the birefringent particles were localized in only one of several lymph nodes visible in the slide. Note that cases with very numerous particle counts by light microscopy are designated simply as greater than a certain threshold.

fully de-identified and serve for identification purposes within the table only. The table shows the relationship of the numbers of birefringent particles by light microscopy within histological sections (separately categorized in lymph node and fibroadipose tissue components), and talc particles found by SEM/EDX on the block surface (following the preparation procedure) corresponding to those sections (right-most column). Consistent with our hypotheses, strong correlations using Spearman correlations were indeed evident between a) lymph node counts by light microscopy and the SEM total talc count (r = 0.80, p < 0.0001); and b) total particle counts by light microscopy and the SEM total talc count (r = 0.79, p < 0.0001). Fibroadipose tissue counts by light microscopy did not correlate with SEM total talc counts (r = 0.32, p = not significant). In controlling for correlated observations from the same patient,

Spearman correlations using one record per case were done for the six patients where more than one lymph node specimen was included in the study (among these patients, the specimen with the highest SEM talc count was the one selected). With this adjustment, strong correlations were still observed using Spearman correlations as evident between a) lymph node counts by light microscopy and the SEM total talc count (r = 0.69, p < 0.03); and b) total particle counts by light microscopy and the SEM total talc count (r = 0.74, p < 0.01), Fibroadipose tissue counts by light microscopy did not correlate with SEM total talc counts (r = 0.16, p =not significant).

Figure 4 shows correlative polarizing light microscopy, in situ SEM, and EDX on case 9C from Table 4. Going clockwise from lower left, panel A shows numerous birefringent particles under polarized light microscopy (H&E, 400x) within the macrophages of a left external iliac lymph node. Panel B shows low-power backscattered electron imaging under SEM with several positive particles. Panel C shows an enlarged (cropped) view of the lower right-hand part of panel B. Three particles are labeled - 44, 45, and 46. Panel **D** shows the spectrum for particle 45, which showed an Mg-Si ratio of 0.643. Particle 44 was also within the 5% of the theoretical value of 0.649 and so was considered talc as well. Particle 46 had an Mg-Si ratio of 0.610, which falls just outside the  $0.649 \pm 5\%$  range for talc, and so it was considered a nonspecific magnesium silicate.

A review of the non-talc particles found by in situ SEM in the 10 patients in Table 4 showed an aggregated total of 310, which based on their chemical composition would be regarded as likely birefringent. Of these, the most common were magnesium silicates outside the 5% theoretical range of the Mg-Si atomic weight spectral ratio for talc (113 total particles or 36%), aluminum silicates with or without magnesium (91 total particles or 29%), and calcium without phosphate (41, or 13%), with others accounting for the remaining 22%. Non-fibrous, non-talc silicates are known to have a longer dissolution time than talc in physiologic conditions; the dissolution time for talc is approximately 8 years for a 1 µm particle.<sup>19</sup> Thus, the component of non-talc silicates in pelvic tissues could proportionally rise over sufficient

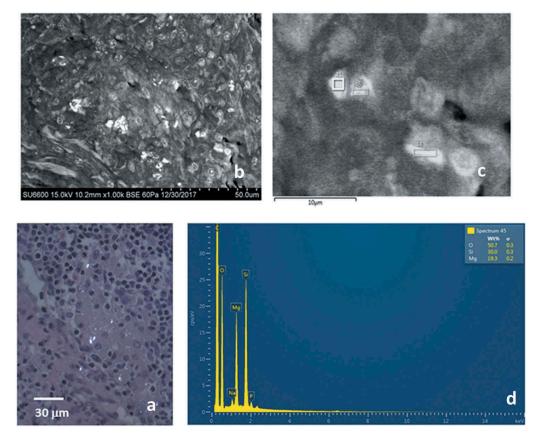


Figure 4. Correlative polarizing light microscopy, in situ SEM, and EDX on case 8C from Table 4. Clockwise from lower left: a, Numerous birefringent particles under polarized light microscopy (H&E, 400x) within the macrophages of a left external iliac lymph node. **b**, Low-power backscattered electron imaging under SEM with several positive particles. **c**, Enlarged (cropped) lower righthand portion of **b**. Three particles are labeled - 44, 45, and 46. **d**, Spectrum for particle 45, which showed an Mg-Si atomic weight ratio of 0.643. Particle 44 was also within the 5% of the theoretical value of 0.649 and so can be considered talc as well. Particle 46 had an Mg-Si atomic weight ratio of 0.610, which falls just outside the 5% range for talc and so can be considered a nonspecific magnesium silicate.

elapsed time (years), even if the original exposure to talc was heavy.

To provide final evidence for our hypothesis that talc is an important part of specimen surface contamination, two authors (SM and JG) rereviewed the 19 slides from the second part of the study (in situ SEM). The goal was to find cases in this group with surface contamination. We did not find any with a score of 3, but two cases (1B and 7A from Table 4) were chosen that, respectively, had contamination scores of 2 and 1 (with 100% agreement by pathologists SM and JG), and substantial amounts of evaluable surface area. On polarizing light microscopy, these cases showed a mixture of larger paper debris fragments and smaller (1-10 µm) birefringent particulates along the surface similar to those previously seen for many Table 1 cases., Respectively, for 1B and 7A, 13 and 5 small birefringent particulates were

found by thorough examination of their surfaces in addition to larger paper debris. SEM of the tissue surface for block 1B (35 mm<sup>2</sup> analysis area) showed a total of 5 talc particles, and for 7A showed 1 talc particle (50 mm<sup>2</sup> analysis area). Given the 2.5 µm effective section thickness (electron beam analysis depth) and these relatively small surface areas, these SEM talc particle counts are significant, and are consistent with the light microscopic review. Thus, this portion of the study directly showed that surface contamination particles were talc, whereas previously, this had only been strongly implied by the results in Table 1. (See supplementary figure S1). In addition to the talc particles, 44 other exogenous particles were found across tissue surfaces of these two cases by SEM/EDX: 27 external mineral (mainly Si in combination with Mg and/or Al), 6 non-talc Mg-Si minerals, and 11 external metal.

#### **Discussion**

The accurate identification of talc in pelvic tissues is important because it documents exposure by demonstrating the presence of talc in these tissues and provides evidence in support of the role of talc in the epidemiological association with ovarian cancer in case-control studies. <sup>9–13,15</sup> The overall relative risk across the various positive studies is around 1.3, and where tumor histology data have been available for review, several common subtypes (serous carcinoma, endometrioid carcinoma, and serous borderline tumors) are most frequently involved in the association. <sup>11,13</sup>

Talc, when applied to the perineum, is believed to migrate to the upper genital tract, passing through the open tract to the fallopian tubes and eventually reaching the ovaries. 11,16 Talc may also gain access to the lymphatic system as a means of reaching pelvic organs and lymph nodes, 20,21, similar to the route to the pulmonary nodes of talc miners.<sup>22</sup> Lymph nodes of the pelvic region include several anatomic sub-classifications (inguinal, iliac, and paraaortic), with the common theme that they may receive lymphatic efferents from pelvic organs such as the ovaries and perineum and/or secondarily from other lymph nodes in the area. Ovarian carcinoma, especially serous, tends to metastasize early (when just one or two nodes are involved) to paraaortic nodes.<sup>23</sup> Full discussions of the lymphatic drainage/anatomy of the pelvic region are available in the literature. 20,21 Lymph nodes are often sampled during gynecologic surgery for tumor staging and assessment for metastatic disease. However, additional examination of these nodes for talc, especially in settings where genital exposure is known to have occurred, would add insight as to the ability of talc to migrate and lodge within pelvic tissues.

This study supports earlier observations that talc particles, from perineal exposure, can and do migrate to pelvic lymph nodes. Material with the microscopic and spectral features of talc was clearly demonstrated within the lymph node parenchyma in most of our cases, as scattered birefringent particles in the general size range 1–10 µm. Sometimes the material was visible within nodal macrophages, lending strong credence to a lymphatic migration route. Similar particles

were also found in the fibroadipose tissue adjacent to lymph nodes, where they may have arrived via the lymphatic system, but more likely resulted from visibly present surface contamination pushed into the underlying fibroadipose tissue.

Our study took the additional critical step of comparing the light microscopic data to SEM digestion data, thereby going beyond the earlier study by Heller et al. 17 in scope, in addition to examining lymph nodes rather than ovaries. Like that earlier paper, we found high talc particle burdens in some digested samples. But because these correlated with contamination scores, we believe that the digestion counts are not fully reflective of clinically relevant talc exposure or its migration in the tissues. Instead, they are influenced by contamination, such as talc introduced by non-surgical gloves used for handling tissue and in the general lab environment during tissue collection and processing in the pathology laboratory. Thus, tissue digestion should not be regarded as a reliable quantification method for talc or contaminants of talc, especially where the collection and processing steps have not been rigidly controlled from the start. The correlation of contamination scores with counts of birefringent particles in fibroadipose tissue suggests that particles adherent to the surface (through contamination) may be pushed into the soft fibroadipose tissue, since it is typically the most peripheral type of tissue, with the nodal tissue usually deeper and encapsulated with a fibrous tissue capsule. The highly variable talc burdens found by digestive analysis and SEM, spanning approximately three orders of magnitude, are consistent with contamination influence, since the latter would be expected to vary considerably between procurement environments. However, this could also be observed in the range of burdens seen in a clinically exposed population with appropriate lab procedures/controls (Table 4).

Even though contamination played a role in total tissue counts, it was still the case that high talc burdens in the lymph nodes, when present, contributed to the SEM digestate results, hence producing the observed correlation between the two. Thus, it is likely that both contamination and clinically significant lymph node talc are reflected in the SEM digestate data. The main

By showing strong correlations between particle counts (polarized light microscopy) and in situ SEM analysis, the second part of our study demonstrated that the latter alternative is a better method of talc assessment than digestion, because the anatomic landmarks are preserved and surface contamination is not incorporated into the general talc count, as it is with tissue digestion. In combination with other parts of our study, this aspect also showed that the birefringent material in the lymph node tissue, is the clinically significant component related to talc exposure. Surface contamination can still be present, and our demonstration of talc on the surfaces of cases 1B and 7A by in situ SEM lent support to the conclusions from the first (digestion) part of the study.

A major strength of our study was the correlative light microscopic and SEM/EDX data for each case, with examination of anatomic locations in the former. This provided a key perspective in the evaluation of the talc burden data that a digestive study alone would not have given. In fact, this study demonstrates the broader principle that correlative histologic review is important in many areas of pathology - especially where digestion procedures are performed, and where the study of anatomic landmarks are needed to complement data from the latter. This is because the tissue is compartmentalized histologically, with different functions and significance for each component, a fact not always recognized by those who digest tissue routinely and use the resulting product completely in analyses such as Western blotting or mutational assays.<sup>24</sup>

Unfortunately, as part of our study, we were not able to also do *in situ* SEM/EDX on the intact tissues used for digestion in the first group of cases (22 patients). However, by showing that birefringent particles within lymph nodes were strongly correlated with the demonstration of talc inside the nodes by *in situ* SEM/EDX, the second part of our study filled that role, and thus 1)

material in lymph nodes is likely reflective of the clinical exposure, 2) in this clinical setting and given our results, a substantial proportion of this birefringent material is likely to be talc, 3) surface contamination is common, and so with *in situ* SEM, it is important to discern the anatomic landmarks, and avoid analyzing surface particulates (as shown by our direct demonstration of talc on the surfaces of cases 1B and 7A in our auxiliary study to the cases in Table 4).

In addition to talc, much other commonly found birefringent material, such as that described in the Results section for the SEM analysis, is likely nonspecific particulate material which finds its way into the perineum through general living and hygiene practices. Another important point is that seeing particles by in situ microscopy, both light and SEM, requires a relatively large amount of material distributed within the tissues in order to find it. As a demonstration of this principle, Roggli and Pratt<sup>25</sup> showed that finding one asbestos body in a tissue section was indicative of at least 100 fibers per gram of tissue. The calculations we used to estimate particles/cm<sup>3</sup> of tissue volume (Table 1), starting with a count of birefringent particles in tissue sections, illustrate a similar principle.

In the long-studied and debated association between talc exposure and ovarian cancer, our study provides additional evidence that talc may enter pelvic tissues and ultimately be detected and measured in regional lymph nodes, and this relationship became especially strong when clinical use data was considered and surface contamination was corrected for statistically. This adds perspective to the known migratory capabilities and overall biological role/impact of talc. For some of the more heavily exposed cases in the second part of the study, we noticed that the large majority of birefringent material was localized in a single node, among several present on a given slide. This suggested that pelvic drainage/migration pathways for talc may be very specific, and focused on one or relatively few nodes as an endpoint perhaps consistent with the concept of sentinel nodes in oncologic surgery.<sup>26</sup>

Our findings also suggest that in patients with ovarian cancer, clinicians may want to make broader inquiries into the past and present use of talc by their patients. Similarly, pathologists may wish to pay greater attention to sampled regional lymph nodes. In addition to the usual study of these nodes for metastases, they may wish to examine macrophages more closely for exogenous particles including by polarized light. A positive finding may trigger clinical inquiries about exposure where it was not previously suspected. Our findings yield important insights as to the ability of talc to migrate to nodes, and under what conditions its identification in nodes and clinically meaningful tissues is when not.

In conclusion, talc contamination of the surface of surgical pathology specimens is common. Exposure (such as perineal application), whether known clinically or not, often results in significant deposition of talc in the tissues. Correlative light microscopy is needed to assess the possibility of lab contamination, and to determine if talc is truly present in clinically meaningful locations in lymph nodes or other tissues.

#### **Declaration of Interest Statement**

The authors declare the following competing financial interest(s): JJG, DC and WW have served as consultants and provided expert testimony in talc and other environmental litigation. SM, YF, RS, MK, and LS report no conflicts of interest.

#### **Funding**

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# Exhibit 78

Public Health Service

Food and Drug Administration College Park, MD 20740

APR 1 - 2014

Samuel S. Epstein, M.D. Cancer Prevention Coalition University of Illinois at Chicago School of Public Health, MC 922 2121 West Taylor Street, Rm. 322 Chicago, Illinois 60612

RE: Docket Numbers 94P-0420 and FDA-2008-P-0309-0001/CP

Dear Dr. Epstein:

This letter is in response to your two Citizen Petitions dated November 17, 1994 and May 13, 2008, requesting that the Food and Drug Administration (FDA or the Agency) require a cancer warning on cosmetic talc products. Your 1994 Petition requests that all cosmetic talc bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." Additionally, your 2008 Petition requests that cosmetic talcum powder products bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer." Further, both of your Petitions specifically request, pursuant to 21 CFR 10.30(h)(2), a hearing for you to present scientific evidence in support of this petition.

We have carefully considered both of your Petitions. We are committed to the protection of the public health and share your interest in reducing the risk of ovarian cancer. Current regulations state that cosmetic products shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with a product. FDA may publish a proposal to establish a regulation prescribing a warning statement on behalf of a petitioner if the petition is supported by adequate scientific basis on reasonable grounds.

After careful review and consideration of the information submitted in your Petitions, the comments received in response to the Petitions, and review of additional scientific information, this letter is to advise you that FDA is denying your Petitions. FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.

For this reason and for the additional reasons described below, FDA is denying your Petitions.

Page 2 – Dr. Epstein

#### I. Discussion

The basis of your request, throughout both Petitions, can be summarized as comprising three major points:

- 1. Talc may be associated with asbestos.
- 2. Talc is a carcinogen based on the findings of a 1993 National Toxicology Program study.
- 3. Epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

As the points you raise in your Petitions concern the chemistry and toxicology of talc, the epidemiology associated with talc use, and the etiology of ovarian cancer, commensurate reviews were conducted to assess your request.

#### **Chemistry Findings:**

Asbestos is a known carcinogen and your first major point is that talc may be associated with asbestos. As evidence that talc cosmetic products contain asbestos, you first cite a 1968 survey of 22 talcum products that found fiber content averaging 19% in all 22 products. This author further concludes that "the fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits ..."

You then cite a follow up study from 1971-1975 that examined 21 samples of consumer talcums and powder and concluded that cosmetic grade talc was not used exclusively in these products. This study found the presence of asbestiform anthophyllite and tremolite, chrysotile, and quartz. From these two citations, one may infer that currently available talc-containing cosmetic products are presently contaminated with asbestos, a known carcinogen. Unfortunately, you did not present any original data on the chemical composition of talc currently being used in cosmetics talc products or data linking these findings to currently used talc.

It has been reported in the scientific literature that most talc products in world trade are impure as a result of the geological processes involved in the formation of talc deposits. Further, talc containing asbestos fibers such as tremolite asbestos or chrysotile are sometimes encountered. However, large deposits of high purity, asbestos-free talc do exist and talc purification techniques have been developed which can be used to improve talc quality. Thus, while it has been reported in the past that cosmetic talc has been contaminated with asbestos, it has been also reported that asbestos-free talc deposits do exist. In addition, techniques do exist for the purification of talc in order to improve its quality. You have not provided evidence that asbestos contaminated talc-containing cosmetic products are currently being marketed, since the data submitted is almost 40 years old.

#### Page 3 – Dr. Epstein

Because safety questions about the possible presence of asbestos in talc are raised periodically, in 2009 FDA conducted an exploratory survey of currently marketed cosmetic-grade raw material talc and finished cosmetic products containing talc. This survey analyzed cosmetic-grade raw material talc from four suppliers out of a possible group of nine suppliers we had requested talc samples from, along with thirty-four talc-containing cosmetic products currently available in the Washington, D.C. metropolitan area for the presence of asbestos. In order to cover as broad a product range as possible, samples identified for testing included low, medium, and high priced products, along with some from "niche" markets. The cosmetic products identified as containing talc included eye shadow, blush, foundation, face powder, and body powder.

The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc. While FDA found this data informative, the results were limited by the fact that only four suppliers submitted samples and by the number of products tested. They do not prove that all talc-containing cosmetic products currently marketed in the United States are free of asbestos contamination. As always, when potential public health concerns are raised, we will continue to monitor for new information and take appropriate actions to protect the public health. You may wish to see more on this survey on our website at <a href="http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184.htm">http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184.htm</a>.

## **Toxicology Findings:**

Your second major point is that talc is a carcinogen with or without the presence of asbestos-like fibers. The basis to this claim is that in 1993, the National Toxicology Program (NTP) published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity.

This NTP report concluded that cosmetic-grade talc caused tumors in animals, even though no asbestos-like fibers were found. The report made the following observations:

- There was some evidence of carcinogenic activity in non-asbestiform talc from inhalation studies in male rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland.
- There was clear evidence of carcinogenic activity of talc in female rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland.
- There was no evidence of carcinogenic activity of talc in male or female mice exposed to 6 or 18 mg/cubic meter.

However, this study lacks convincing scientific support because of serious flaws in its design and conduct, including:

- The investigators used micronized talc instead of consumer-grade talc resulting in the experimental protocol not being reflective of human exposure conditions in terms of particle size.

#### Page 4 – Dr. Epstein

- Investigators conceded that they had problems with the aerosol generation system; whereby, the target aerosol concentrations were either excessive or not maintained during 26 of the 113-122 weeks of the study.
- The study did not include positive and negative dust controls which would have permitted an "exact assessment" of the tale's carcinogenicity relative to the two control dusts.

In light of these shortcomings, a panel of experts at the 1994 ISRTP/FDA workshop declared that the 1993 NTP study has no relevance to human risk.

In addition, we reviewed relevant toxicity literature (consisting of 15 articles from 1980 to 2008), not cited in your Petitions, to determine if there was additional support at this point in time to for your suggested warning label. Scientific literature on studies of acute exposure effects, subchronic exposure effects, chronic exposure or carcinogenicity effects, developmental or reproductive toxicity, and genotoxicity effects were reviewed. As a result of the review of this relevant literature, FDA did not find enough additional support at this point in time for your suggested warning label.

### Epidemiology and Etiology Findings:

Your third major point is that epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

After consideration of the scientific literature submitted in support of both Citizen Petitions, FDA found:

- The exposure to talc is not well-characterized; it is not known if the talc referred to in the scientific studies was free of asbestos contamination; various consumer brands or lots of talc were not identified; and contamination of talc by asbestiform minerals or other structurally similar compounds was not ruled out.
- 2 Several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled confounding that result in spurious positive associations between talc use and ovarian cancer risk.
- Results of case-controls studies do not demonstrate a consistent positive association across studies; some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0 and dose-response evidence is lacking.
- 4 A cogent biological mechanism by which talc might lead to ovarian cancer is lacking; exposure to talc does not account for all cases of ovarian cancer; and

#### Page 5- Dr. Epstein

- 5 there was no scientific consensus on the proportion of ovarian cancer cases that may be caused by talc exposure.
- 6 The conclusion of the International Agency for Research on Cancer that epidemiological studies provide limited evidence for the carcinogenicity of perineal use of talc based body powder and the IARC classification of bodypowder talc as group-2B, a possible carcinogen to human beings, is persuasive, but the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer.

Per the <u>etiology</u> review, approximately 10% of epithelial ovarian cancers are associated with inherited mutations. The remaining 90% of epithelial ovarian cancers are not related to these genetic mutations are non-hereditary. They have been historically classified based on histology as borderline/low malignant potential, serous, endometrioid, mucinous, and clear-cell.

Two theories have historically dominated on the cause of epithelial ovarian cancer and these are the "incessant ovulation hypothesis" and the "gonadotropin hypothesis." In addition to these endogenous factors, the role of exogenous factors via retrograde transport of noxious substances (e.g. carcinogens, particulates such as talc and asbestos, endometriosis and infectious agents) from the vagina and uterus into the Fallopian Tubes and peritoneal cavity have been studied extensively as a possible risk factor for ovarian cancer.

While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers. However, there has been no conclusive evidence to support causality.

The best evidence for an association or causal relationship between genital talc exposure and ovarian cancer comes from epidemiologic data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking.

## Request for hearing

In addition to your request for a warning label, you also requested a hearing, under 21 CFR 10.30(h)(2), so that you can present scientific evidence in support of your petitions.

Page 6 – Dr. Epstein

Under this regulation, FDA may deny a citizen petition request for a hearing if the data and information submitted (even if accurate), are insufficient to justify the determination urged. In consideration of your request, we conducted an expanded literature search dating from the filing of the petition in 2008 through January 2014. The results of this search failed to identify any new compelling literature data or new scientific evidence.

Since we find that the data and information are insufficient to justify the determination you request and we did not identify any new compelling literature data or new scientific evidence, FDA is also denying your hearing request.

#### II. Conclusion

FDA appreciates the goals of the Cancer Prevention Coalition and FDA supports the goal of reducing the rate of ovarian cancer. Although FDA is denying the Cancer Prevention Coalition's petitions for the reasons discussed above, the Agency shares your commitment to the public health.

Sincerely,

Steven M. Musser, Ph.D.

Deputy Director for Scientific Operations

Center for Food Safety and Applied Nutrition

Drafted: J. Gasper, OCAC, 2/28/14 Comments: L. Katz, OCAC, 3/3/14 Revised: J. Gasper, OCAC, 3/4/14 Cleared: N.Sadrieh, OCAC, 3/4/14 Cleared: LMKatz, OCAC, 3/5/14 Reviewed: FHogue, OCAC: 3/614 Cleared by:Musser:3/13/14

Cleared by:Musser:3/13/14 F/T:SRussell, OCAC 3/18/14

# Exhibit 79

-----x

THIS DOCUMENT RELATES TO

ALL CASES

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VIDEOTAPED DEPOSITION UNDER ORAL EXAMINATION OF SONAL SINGH, M.D., M.P.H.

January 16, 2019, 9:07 a.m.

- - -

REPORTED BY: JANET M. SAMBATARO, RMR, CRR, CLR

- - -

GOLKOW LITIGATION SERVICES
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	Page 2		Page 4
1		1	APPEARANCES: (Continued)
2		2	,
3		3	TUCKER ELLIS
4		4	BY: MICHAEL C. ZELLERS, ESQ.
5		5	515 South Flower Street
6	Deposition of SONAL SINGH, M.D., M.P.H.,	6	Los Angeles, California 90071
7	held at the Beechwood Hotel, 363 Plantation Street,	7	(213) 430-3400
8	Worcester, Massachusetts, pursuant to Agreement	8	michael.zellers@tuckerellis.com
9	before Janet Sambataro, a Registered Merit Reporter,	9	Representing the Defendant, Johnson & Johnson,
10 11	Certified Realtime Reporter, Certified LiveNote	10 11	Johnson & Johnson Consumer Companies, Inc.
12	Reporter, and a Notary Public within and for the Commonwealth of Massachusetts, on January 16, 2019,	12	
13	commencing at 9:07 a.m.	13	
14	commencing at 9.07 d.m.	14	DRINKER BIDDLE AND REATH, LLP
15		15	BY: KATHERINE MCBETH, ESQ.
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21		21	Johnson & Johnson Consumer Companies, Inc.
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23		23	~
24		24	- Continued -
25		25	
	Page 3		Page 5
1	APPEARANCES:	1	APPEARANCES: (Continued)
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8	mparfitt@ashcraftlaw.com	8	Imerys Talc America, Inc.
_	Representing the Plaintiffs	ו פ	
1 ∩		1 0	COLIGHLIN DUEEN LLP
10 11	LEVIN PAPANTONIO	10 11	COUGHLIN DUFFY LLP BY: MARYAM M MESEHA ESO
11	LEVIN PAPANTONIO BY: CHRISTOPHER V. TISI, ESO.	11	BY: MARYAM M. MESEHA, ESQ.
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11 12		11 12	BY: MARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962
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11 12 13 14 15 16 17	BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen Street Pensacola, Florida 32502 (850) 435-7000	11 12 13 14 15 16 17	BY: MARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.
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11 12 13 14 15 16 17 18 19 20 21	BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen Street Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com Representing the Plaintiffs  RESTAINO LAW LLC BY: JOHN RESTAINO, ESQ. 130 Forest Street	11 12 13 14 15 16 17 18 19 20 21	BY: MARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.  TUCKER ELLIS BY: JAMES W. MIZGALA, ESQ. 233 South Wacker Drive Chicago, Illinois 60606
11 12 13 14 15 16 17 18 19 20 21 22	BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen Street Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com Representing the Plaintiffs  RESTAINO LAW LLC BY: JOHN RESTAINO, ESQ. 130 Forest Street Denver, Colorado 80220	11 12 13 14 15 16 17 18 19 20 21 22	BY: MARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.  TUCKER ELLIS BY: JAMES W. MIZGALA, ESQ. 233 South Wacker Drive Chicago, Illinois 60606 (312) 624-6300
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11 12 13 14 15 16 17 18 19 20 21 22	BY: CHRISTOPHER V. TISI, ESQ. 316 South Baylen Street Pensacola, Florida 32502 (850) 435-7000 ctisi@levinlaw.com Representing the Plaintiffs  RESTAINO LAW LLC BY: JOHN RESTAINO, ESQ. 130 Forest Street Denver, Colorado 80220	11 12 13 14 15 16 17 18 19 20 21 22	BY: MARYAM M. MESEHA, ESQ. 350 Mount Kemble Avenue Morristown, New Jersey 07962 (973) 267-0058 mmeseha@coughlinduffy.com Representing Imerys Talc America, Inc.  TUCKER ELLIS BY: JAMES W. MIZGALA, ESQ. 233 South Wacker Drive Chicago, Illinois 60606 (312) 624-6300

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1 1	States" 179 entitled "Tubal Ligation
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25 attachments 21 25 - Continued	escence in the Epithelia
25 attachments 21 25 - Continued	escence in the Epithelia pian Tube Fimbria" 206

3 (Pages 6 to 9)

	D 10		D 10
	Page 10		Page 12
1	EXHIBITS	1	deposition as an expert for the plaintiffs in the
2	Number Description Page	2	Talc MDL; is that correct?
3	Exhibit 26 Article entitled "New Insights	3	A. Yes.
4	into the Pathogenesis of Ovarian	4	Q. You are familiar with depositions?
5	Cancer: Oxidative Stress" 228	5	A. Yes.
6	Exhibit 27 Federal Register, Vol. 81,	6	Q. You've given a number of depositions in
7	No. 243 233	7	your career?
8	Exhibit 28 Document entitled "Interpretation	8	A. I don't know about a number. Yes, I
9	of Epidemiologic Studies on Talc	9	have.
10	and Ovarian Cancer" 244	10	Q. Can you estimate for us the number of
11	Exhibit 29 Article entitled "Association	11	depositions that you've given?
12	between Body Powder Use and Ovarian	12	A. I think I've provided that list in the
13	Cancer: The African American	13	last five years.
14	Cancer Epidemiology Study (AACES) 261	14	Q. I understand. My question is a little
15	Exhibit 30 Article entitled "Does Exposure to	15	different.
16	Asbestos Cause Ovarian Cancer?	16	How many have you given in your career?
17	A Systematic Literature Review and	17	A. I can't tell you in my career. Maybe
18	Meta-analysis" 289	18	ten. Approximately.
19	Exhibit 31 Article entitled "Occupational	19	Q. Have you ever testified at trial?
20	Exposure to Asbestos and Ovarian	20	A. No.
21	Cancer: A Meta-analysis" 293	21	Q. You understand today that I'm going to
22	Exhibit 32 Chart 316	22	ask you a number of questions and other counsel
23		23	may as well; correct?
24		24	A. Yes.
25		25	Q. Please don't answer any question that
	Page 11		Page 13
1	PROCEEDINGS	1	you don't understand.
2	THE VIDEOGRAPHER: We are now on the		= =
	THE VIDEOGICAL TIER. WE are now on the	2	Can you do that?
3	record. My name is Jody Urbati. I am a	2 3	Can you do that? A. Yes.
	record. My name is Jody Urbati. I am a		A. Yes.
3	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services.	3	<ul><li>A. Yes.</li><li>Q. If you don't understand a question, let</li></ul>
3 4	record. My name is Jody Urbati. I am a	3 4	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase
3 4 5	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services. Today's date is January 16, 2019, and the time is 9:07 a.m.	3 4 5	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase it, so that we can make it clear to you.
3 4 5 6	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services. Today's date is January 16, 2019, and the time is	3 4 5 6	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase
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3 4 5 6 7 8 9	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services.  Today's date is January 16, 2019, and the time is 9:07 a.m.  This video deposition is being held in Worcester, Massachusetts, in the matter of Talcum Powder Litigation, MDL No. 2738, for the United States District Court, District of New Jersey.	3 4 5 6 7 8	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase it, so that we can make it clear to you. Can you do that? A. Yes.
3 4 5 6 7 8 9	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services.  Today's date is January 16, 2019, and the time is 9:07 a.m.  This video deposition is being held in Worcester, Massachusetts, in the matter of Talcum Powder Litigation, MDL No. 2738, for the United States District Court, District of New Jersey.  The deponent today is Sonal Singh,	3 4 5 6 7 8 9	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase it, so that we can make it clear to you. Can you do that? A. Yes. Q. If you answer a question that I ask, then I'm going to assume that you understood it.
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3 4 5 6 7 8 9 10 11 12	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services.  Today's date is January 16, 2019, and the time is 9:07 a.m.  This video deposition is being held in Worcester, Massachusetts, in the matter of Talcum Powder Litigation, MDL No. 2738, for the United States District Court, District of New Jersey.  The deponent today is Sonal Singh, M.D., M.P.H.  Counsel will be noted on the	3 4 5 6 7 8 9 10 11	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase it, so that we can make it clear to you. Can you do that? A. Yes. Q. If you answer a question that I ask, then I'm going to assume that you understood it. Is that fair? A. Yes. Q. You are here today pursuant to a Notice
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services.  Today's date is January 16, 2019, and the time is 9:07 a.m.  This video deposition is being held in Worcester, Massachusetts, in the matter of Talcum Powder Litigation, MDL No. 2738, for the United States District Court, District of New Jersey.  The deponent today is Sonal Singh, M.D., M.P.H.  Counsel will be noted on the stenographic record.  The court reporter is Janet Sambataro and will now swear in the witness.  SONAL SINGH, M.D., M.P.H., having been duly sworn, after presenting identification in the form of a driver's license, deposes and says as follows:  DIRECT EXAMINATION  BY MR. ZELLERS:	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase it, so that we can make it clear to you. Can you do that? A. Yes. Q. If you answer a question that I ask, then I'm going to assume that you understood it. Is that fair? A. Yes. Q. You are here today pursuant to a Notice of Deposition, which we have marked as Exhibit 1. (Notice of Oral and Videotaped Deposition of Sonal Singh and Duces Tecum marked Exhibit 1.) BY MR. ZELLERS: Q. Is that correct? A. Yes. MR. ZELLERS: Katherine, when I mark an exhibit, I'm going to need to hand them to you.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services.  Today's date is January 16, 2019, and the time is 9:07 a.m.  This video deposition is being held in Worcester, Massachusetts, in the matter of Talcum Powder Litigation, MDL No. 2738, for the United States District Court, District of New Jersey.  The deponent today is Sonal Singh, M.D., M.P.H.  Counsel will be noted on the stenographic record.  The court reporter is Janet Sambataro and will now swear in the witness.  SONAL SINGH, M.D., M.P.H., having been duly sworn, after presenting identification in the form of a driver's license, deposes and says as follows:  DIRECT EXAMINATION  BY MR. ZELLERS:  Q. State your name, please.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase it, so that we can make it clear to you. Can you do that? A. Yes. Q. If you answer a question that I ask, then I'm going to assume that you understood it. Is that fair? A. Yes. Q. You are here today pursuant to a Notice of Deposition, which we have marked as Exhibit 1. (Notice of Oral and Videotaped Deposition of Sonal Singh and Duces Tecum marked Exhibit 1.) BY MR. ZELLERS: Q. Is that correct? A. Yes. MR. ZELLERS: Katherine, when I mark an exhibit, I'm going to need to hand them to you. MS. MCBETH: Sure.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	record. My name is Jody Urbati. I am a videographer for Golkow Litigation Services.  Today's date is January 16, 2019, and the time is 9:07 a.m.  This video deposition is being held in Worcester, Massachusetts, in the matter of Talcum Powder Litigation, MDL No. 2738, for the United States District Court, District of New Jersey.  The deponent today is Sonal Singh, M.D., M.P.H.  Counsel will be noted on the stenographic record.  The court reporter is Janet Sambataro and will now swear in the witness.  SONAL SINGH, M.D., M.P.H., having been duly sworn, after presenting identification in the form of a driver's license, deposes and says as follows:  DIRECT EXAMINATION  BY MR. ZELLERS:	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. If you don't understand a question, let me know, and I'll repeat the question or rephrase it, so that we can make it clear to you. Can you do that? A. Yes. Q. If you answer a question that I ask, then I'm going to assume that you understood it. Is that fair? A. Yes. Q. You are here today pursuant to a Notice of Deposition, which we have marked as Exhibit 1. (Notice of Oral and Videotaped Deposition of Sonal Singh and Duces Tecum marked Exhibit 1.) BY MR. ZELLERS: Q. Is that correct? A. Yes. MR. ZELLERS: Katherine, when I mark an exhibit, I'm going to need to hand them to you.

4 (Pages 10 to 13)

	Page 14		Page 16
1	BY MR. ZELLERS:	1	A. Yes.
2	Q. Did you have an opportunity to review	2	Q. If at any time today you need to look
3	Deposition Exhibit 1 before today's deposition?	3	at any of those documents, they're available, and
4	A. Yes.	4	you're free to do that. Understood?
5	Q. Have you brought with you or provided	5	A. It is understood.
6	to counsel for production all materials in your	6	Q. You had attached or provided with your
7	possession that are responsive to the Notice of	7	report a curriculum vitae, which I understand has
8	Deposition?	8	been updated; is that right?
9	A. I have.	9	A. Yes.
10	MR. ZELLERS: I will mark, as	10	MR. ZELLERS: We will mark your updated
11	Deposition Exhibit 2, your report in this matter	11	CV or curriculum vitae as Deposition Exhibit 3.
12	dated November 16 of 2018.	12	(Sonal Singh, MD, MPH, FACP,
13	(Rule 26 Expert Report of Sonal	13	curriculum vitae marked Exhibit 3.)
14	Singh, MD, MPH marked Exhibit 2.)	14	MR. ZELLERS: Folks, I believe that
15	BY MR. ZELLERS:	15	Ms. Parfitt has distributed to you, before the
16	Q. Is that correct?	16	deposition, Exhibit 3.
17	A. It is. It doesn't have the references.	17	BY MR. ZELLERS:
18	Q. Deposition Exhibit 2 is just a copy of	18	Q. Can you tell us, just briefly, in what
19	your report itself. It ends at Page 66.	19	respect has Exhibit 3 been updated from the CV
20	Attached to your report were some additional	20	that was produced with your report in this
21	materials; is that right?	21	matter?
22	A. Yeah. Yeah. I just want to make sure	22	A. A few publications, and then I was
23	because when I refer to the report, I understand	23	elected to the fellowship of the American College
24	it to include references and tables and so on.	24	of Physicians on January 1st. So I'm an FACP,
25	Q. Your report includes everything that	25	and, yes, just a couple of publications,
	Page 15		Page 17
1	was produced by plaintiffs' counsel as part of	1	presentations.
2	that report; is that right?	2	Q. Is the curriculum vitae that we have
3	And, Dr. Singh, I'm going to mark separately	3	marked as Deposition Exhibit 3 complete and up to
4	a number of the attachments	4	date?
5	A. Okay.	5	A. Yes. Up to January 3rd. Yes.
6	Q to your report. Right now, I'm just	6	Q. Of 2019?
7	trying to identify, is the body of your report	7	A. 2019. Yeah.
8	A 37 1		
-	A. Yeah.	8	Q. Are there any further additions or
9	Q what we have identified and marked	9	Q. Are there any further additions or corrections that need to be made to that CV?
9 10	Q what we have identified and marked as Exhibit 2?	9 10	corrections that need to be made to that CV?  A. No.
9 10 11	<ul><li>Q what we have identified and marked as Exhibit 2?</li><li>MS. PARFITT: And if I may,</li></ul>	9 10 11	corrections that need to be made to that CV?  A. No.  MR. ZELLERS: Deposition Exhibit 4 is
9 10 11 12	<ul> <li>Q what we have identified and marked as Exhibit 2?</li> <li>MS. PARFITT: And if I may,</li> <li>Mr. Zellers, object. The body of the report,</li> </ul>	9 10 11 12	corrections that need to be made to that CV?  A. No.  MR. ZELLERS: Deposition Exhibit 4 is the list of references from your report. And
9 10 11 12 13	<ul> <li>Q what we have identified and marked as Exhibit 2?</li> <li>MS. PARFITT: And if I may,</li> <li>Mr. Zellers, object. The body of the report,</li> <li>Dr. Singh may include as the body of the report</li> </ul>	9 10 11 12 13	corrections that need to be made to that CV?  A. No.  MR. ZELLERS: Deposition Exhibit 4 is the list of references from your report. And that goes from Page 67 to Page 75.
9 10 11 12 13 14	Q what we have identified and marked as Exhibit 2? MS. PARFITT: And if I may, Mr. Zellers, object. The body of the report, Dr. Singh may include as the body of the report plus all of its attachments.	9 10 11 12 13 14	corrections that need to be made to that CV?  A. No.  MR. ZELLERS: Deposition Exhibit 4 is the list of references from your report. And that goes from Page 67 to Page 75.  Q. Is that correct?
9 10 11 12 13 14	Q what we have identified and marked as Exhibit 2?  MS. PARFITT: And if I may,  Mr. Zellers, object. The body of the report,  Dr. Singh may include as the body of the report plus all of its attachments.  So just so the record is clear, but I	9 10 11 12 13 14 15	corrections that need to be made to that CV?  A. No.  MR. ZELLERS: Deposition Exhibit 4 is the list of references from your report. And that goes from Page 67 to Page 75.  Q. Is that correct?  A. Yes.
9 10 11 12 13 14 15	Q what we have identified and marked as Exhibit 2?  MS. PARFITT: And if I may,  Mr. Zellers, object. The body of the report,  Dr. Singh may include as the body of the report plus all of its attachments.  So just so the record is clear, but I understand how you'd like to conduct it, and	9 10 11 12 13 14 15 16	corrections that need to be made to that CV?  A. No.  MR. ZELLERS: Deposition Exhibit 4 is the list of references from your report. And that goes from Page 67 to Page 75.  Q. Is that correct?  A. Yes.  (List of references marked
9 10 11 12 13 14 15 16	Q what we have identified and marked as Exhibit 2?  MS. PARFITT: And if I may, Mr. Zellers, object. The body of the report, Dr. Singh may include as the body of the report plus all of its attachments.  So just so the record is clear, but I understand how you'd like to conduct it, and that's fine.	9 10 11 12 13 14 15 16 17	corrections that need to be made to that CV?  A. No.  MR. ZELLERS: Deposition Exhibit 4 is the list of references from your report. And that goes from Page 67 to Page 75.  Q. Is that correct?  A. Yes.  (List of references marked Exhibit 4.)
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9 10 11 12 13 14 15 16 17 18 19 20	Q what we have identified and marked as Exhibit 2?  MS. PARFITT: And if I may, Mr. Zellers, object. The body of the report, Dr. Singh may include as the body of the report plus all of its attachments.  So just so the record is clear, but I understand how you'd like to conduct it, and that's fine.  MR. ZELLERS: Understood. BY MR. ZELLERS: Q. Your counsel today has provided us with	9 10 11 12 13 14 15 16 17 18 19 20	corrections that need to be made to that CV?  A. No.  MR. ZELLERS: Deposition Exhibit 4 is the list of references from your report. And that goes from Page 67 to Page 75.  Q. Is that correct?  A. Yes.  (List of references marked Exhibit 4.)  MR. ZELLERS: Deposition Exhibit 5 is also from your report, and it's a listing of additional materials and data considered.
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5 (Pages 14 to 17)

	Page 18		Page 20
1	MR. ZELLERS: Deposition Exhibit 6 is	1	testimony list, several additional documents that
2	an updated list of materials that defendants were	2	counsel for plaintiffs has indicated are
3	provided on January 13th of 2019.	3	responsive to the deposition notice.
4	(Updated Materials List marked	4	Let me mark these. I have not had a chance
5	Exhibit 6.)	5	to look at them yet substantively.
6	BY MR. ZELLERS:	6	THE WITNESS: Sure.
7	Q. Is that correct?	7	MR. ZELLERS: But I will and may, at a
8	A. Yes.	8	later time today, have some questions for you.
9	MR. ZELLERS: Folks, I need one more of	9	THE WITNESS: Actually, I will say
10	those back. Can I get one more? Thank you.	10	there's a substantive document that's not here.
11	Deposition Exhibit 7 is a listing of	11	That's the table of rating that I created for the
12	the trial testimony and expert deposition	12	report, and that should be part of the report.
13	testimony that you have provided in the last five	13	MR. ZELLERS: Let me see if I can find
14	years.	14	that.
15	(List of Trial Testimony marked	15	BY MR. ZELLERS:
16	Exhibit 7.)	16	Q. It would be helpful to have that marked
17	BY MR. ZELLERS:	17	as well; is that right?
18	Q. Is that right?	18	A. Yes.
19	A. Yes. Actually, I have provided them an	19	MR. ZELLERS: I will mark, as
20	update, as well, of that. So I don't know if	20	Deposition Exhibit 9, the Amstar rating of
21	that was with you, but	21	reviews, Pages 77 and 78 from your full report.
22	Q. You have brought with you today an	22	(Table 1 AMSTAR marked
23	updated list of expert deposition testimony for	23	Exhibit 9.)
24	the last five years?	24	BY MR. ZELLERS:
25	A. Yes. No. 7 is the update.	25	Q. Is that right?
	Page 19		Page 21
1	MR. ZELLERS: We will mark the updated		
	MR. ZELLERS. WE WIII Mark the updated	1	A. Thank you.
2	trial testimony list as Deposition Exhibit 8.	1 2	A. Thank you.  MR. TISI: That was No. 9?
2			-
	trial testimony list as Deposition Exhibit 8.	2	MR. TISI: That was No. 9?
3	trial testimony list as Deposition Exhibit 8.  (List of Expert Deposition	2 3	MR. TISI: That was No. 9? MR. ZELLERS: No. 9.
3 4	trial testimony list as Deposition Exhibit 8.  (List of Expert Deposition marked Exhibit 8.)	2 3 4	MR. TISI: That was No. 9? MR. ZELLERS: No. 9. Let's go off the stenographic record.
3 4 5	trial testimony list as Deposition Exhibit 8.  (List of Expert Deposition marked Exhibit 8.)  MR. ZELLERS: And I understand that's	2 3 4 5	MR. TISI: That was No. 9?  MR. ZELLERS: No. 9.  Let's go off the stenographic record.  You can keep the video going.
3 4 5 6	trial testimony list as Deposition Exhibit 8.  (List of Expert Deposition marked Exhibit 8.)  MR. ZELLERS: And I understand that's out of order, but I premarked one other exhibit.	2 3 4 5 6	MR. TISI: That was No. 9? MR. ZELLERS: No. 9. Let's go off the stenographic record. You can keep the video going. (Discussion off the stenographic record.)
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6 (Pages 18 to 21)

	Page 22		Page 24
1	marked Exhibit 11.)	1	A. Yes.
2	BY MR. ZELLERS:	2	MS. PARFITT: And for the record,
3	Q. The documents that were produced by	3	Mr. Zellers, and we can go ahead and redact the
4	counsel this morning, Deposition Exhibit 11, is a	4	copy later, but just so the record is clear, that
5	June 1st, 2015 letter with Janssen	5	communication at the top to me from Dr. Singh was
6	Pharmaceuticals at the top to you from a	6	simply, we asked him, do you have any
7	Dr. Zanca. Is that right?	7	communications, and then he sent it to me.
8	A. Yes.	8	MR. TISI: We'll redact the part with
9	Q. Is this inviting you to a program?	9	your agreement.
10	A. Yes. Consultation for a panel on	10	MR. ZELLERS: Yes. We can do that at a
11	products discussion manufactured by Johnson and	11	break
12	Janssen Pharmaceuticals.	12	MS. PARFITT: At a break.
13	Q. You're producing this in response to	13	MR. ZELLERS: or, you know, at the
14	the request asking for all communications between	14	conclusion
15	yourself and any Johnson & Johnson company; is	15	MS. PARFITT: I appreciate that. Thank
16	that right?	16	you.
17	A. That's what I understood it to be,	17	MR. ZELLERS: of the deposition.
18	but yeah.	18	BY MR. ZELLERS:
19	Q. You've gone and you've made a search,	19	Q. Do you strike that.
20	and in the search for additional records	20	The date of your e-mail at the bottom of
21	responsive to the Notice of Deposition, which we	21	Page 1 is December 13th of 2018; is that right?
22	marked as Exhibit 1, you have brought these	22	A. Yes.
23	additional documents that we're marking here; is	23	Q. You had been retained as an expert?
24	that correct?	24	A. Yes.
25	A. Well, I wouldn't say I made a search.	25	Q. And had submitted, in fact, your expert
	Page 23		Page 25
1	Page 23  I sort of read it, you know, decided, okay, what	1	Page 25 report that we have marked previously; is that
1 2		1 2	
	I sort of read it, you know, decided, okay, what	1	report that we have marked previously; is that
2	I sort of read it, you know, decided, okay, what other additional things that are requested and,	2	report that we have marked previously; is that right?
2	I sort of read it, you know, decided, okay, what other additional things that are requested and, you know, recalled that I had had this	2 3	report that we have marked previously; is that right?  A. Yes.
2 3 4	I sort of read it, you know, decided, okay, what other additional things that are requested and, you know, recalled that I had had this interaction with Johnson & Johnson employees.  Q. Are you comfortable that you have brought with you today all of the documents that	2 3 4	report that we have marked previously; is that right?  A. Yes.  Q. In this communication, Exhibit 12, do
2 3 4 5	I sort of read it, you know, decided, okay, what other additional things that are requested and, you know, recalled that I had had this interaction with Johnson & Johnson employees.  Q. Are you comfortable that you have	2 3 4 5	report that we have marked previously; is that right?  A. Yes.  Q. In this communication, Exhibit 12, do you at all identify yourself as a paid, retained expert for the plaintiffs in the talc litigation?  A. No. This was just a communication
2 3 4 5 6	I sort of read it, you know, decided, okay, what other additional things that are requested and, you know, recalled that I had had this interaction with Johnson & Johnson employees.  Q. Are you comfortable that you have brought with you today all of the documents that	2 3 4 5 6	report that we have marked previously; is that right?  A. Yes.  Q. In this communication, Exhibit 12, do you at all identify yourself as a paid, retained expert for the plaintiffs in the talc litigation?
2 3 4 5 6 7 8	I sort of read it, you know, decided, okay, what other additional things that are requested and, you know, recalled that I had had this interaction with Johnson & Johnson employees.  Q. Are you comfortable that you have brought with you today all of the documents that are responsive to the Notice of Deposition?  A. Yes.  (Email string with top e-mail	2 3 4 5 6 7 8	report that we have marked previously; is that right?  A. Yes. Q. In this communication, Exhibit 12, do you at all identify yourself as a paid, retained expert for the plaintiffs in the talc litigation?  A. No. This was just a communication about references, and I did not.  MR. ZELLERS: Dr. Singh, the next set
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	I sort of read it, you know, decided, okay, what other additional things that are requested and, you know, recalled that I had had this interaction with Johnson & Johnson employees.  Q. Are you comfortable that you have brought with you today all of the documents that are responsive to the Notice of Deposition?  A. Yes.  (Email string with top e-mail dated December 27, 2018 marked Exhibit 12.)  MR. ZELLERS: All right.  BY MR. ZELLERS:  Q. Deposition Exhibit 12 is an e-mail string. The very last e-mail is from you towell, it's to Michelle Parfitt. I'm assuming that you were forwarding to Ms. Parfitt just the e-mail below, which is from you to Mr. Restaino and then, apparently, the substantive e-mail is at the bottom of the first page of Exhibit 12.  And this is a communication e-mail from you to Lee-May Chen and others; is that right?  A. Yes.  Q. The subject is "Up-to-date references."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	report that we have marked previously; is that right?  A. Yes. Q. In this communication, Exhibit 12, do you at all identify yourself as a paid, retained expert for the plaintiffs in the talc litigation?  A. No. This was just a communication about references, and I did not.  MR. ZELLERS: Dr. Singh, the next set of documents that you have brought with you and that we will mark collectively as Exhibit 13 are your invoices.  (Invoices from Dr. Singh marked Exhibit 13.)  BY MR. ZELLERS: Q. The first invoice is dated July 14 of 2010. There's a total of five invoices.  The last invoice is from July 11, 2018, to November 19, 2018. Is that right?  A. It should be 2017, not 2010. I'm sorry. You mentioned 2010.  Q. And the date is 2017?  A. Yeah. I wanted to correct that.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I sort of read it, you know, decided, okay, what other additional things that are requested and, you know, recalled that I had had this interaction with Johnson & Johnson employees.  Q. Are you comfortable that you have brought with you today all of the documents that are responsive to the Notice of Deposition?  A. Yes.  (Email string with top e-mail dated December 27, 2018 marked Exhibit 12.)  MR. ZELLERS: All right.  BY MR. ZELLERS:  Q. Deposition Exhibit 12 is an e-mail string. The very last e-mail is from you towell, it's to Michelle Parfitt. I'm assuming that you were forwarding to Ms. Parfitt just the e-mail below, which is from you to Mr. Restaino and then, apparently, the substantive e-mail is at the bottom of the first page of Exhibit 12.  And this is a communication e-mail from you to Lee-May Chen and others; is that right?  A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	report that we have marked previously; is that right?  A. Yes. Q. In this communication, Exhibit 12, do you at all identify yourself as a paid, retained expert for the plaintiffs in the talc litigation?  A. No. This was just a communication about references, and I did not.  MR. ZELLERS: Dr. Singh, the next set of documents that you have brought with you and that we will mark collectively as Exhibit 13 are your invoices.  (Invoices from Dr. Singh marked Exhibit 13.)  BY MR. ZELLERS: Q. The first invoice is dated July 14 of 2010. There's a total of five invoices.  The last invoice is from July 11, 2018, to November 19, 2018. Is that right?  A. It should be 2017, not 2010. I'm sorry. You mentioned 2010.  Q. And the date is 2017?

	Page 26		Page 28
1	substantively, the invoices.	1	(Plaintiffs' Steering
2	A. Sure.	2	Committee's Response and Objections to the
3	Q. And I don't think we have a complete	3	Notice of Oral and Videotaped Deposition of
4	copy. I'm going to ask you some questions in a	4	Sonal Singh and Duces Tecum marked Exhibit
5	bit.	5	14.)
6	A. We do have a complete copy. I mean, in	6	MR. ZELLERS: Back on the stenographic
7	terms of	7	record.
8	Q. No. I understand that Exhibit 13 is a	8	Dr. Singh, at the request of
9	complete copy of your invoices.	9	plaintiffs' counsel, we will mark and
10	A. Yeah.	10	incorporate, as an Exhibit 14, the objections
11	Q. That you now have the copy in front of	11	that plaintiffs have filed to the deposition
12	you. I don't have the copy in front of me. Keep	12	notice.
13	it. I'll have some questions for you a bit	13	MS. PARFITT: Thank you.
14	later.	14	BY MR. ZELLERS:
15	Have we now marked all documents that are	15	Q. Have we identified and marked all of
16	responsive to the Notice of Deposition which you	16	the documents that you have produced pursuant to
17	have produced here today? And let me withdraw	17	the Notice of Deposition?
18	that.	18	A. We have.
19	Have we now marked all of the documents that	19	Q. To your knowledge, there are no
20	you have produced in response to the Notice of	20	additional documents that you have in your
21	Deposition?	21	possession to produce; is that right?
22	A. Yeah. And I think that, you know,	22	A. I don't have any additional documents.
23	there were some updated materials that I reviewed	23	Q. The report that we have marked as
24	that are part of this list.	24	Deposition Exhibit 10, does that contain all of
25	Q. All right. And we need to be more	25	the opinions that you intend to offer at trial?
	Page 27		Page 29
1	specific	1	A. Actually, it's Deposition Exhibit 2.
2	A. Sure.	2	Q. I understand.
3	Q as you understand from doing this	3	A. Sorry. I'm a little confused here.
4	before.	4	Q. That's fine. We don't want you to be
5	37 6 1 4 11 4 6 1 4 1		
	You are referring to the list of updated	5	confused. And I asked you in the beginning to
6	materials that was produced about a week ago?	5 6	confused. And I asked you in the beginning to tell me if you were getting confused.
6 7			
	materials that was produced about a week ago?	6	tell me if you were getting confused.
7	materials that was produced about a week ago? A. Yeah. Q. And that is Deposition Exhibit well, strike that.	6 7 8 9	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.
7 8	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well,	6 7 8	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments
7 8 9	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that	6 7 8 9	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.
7 8 9 10	materials that was produced about a week ago? A. Yeah. Q. And that is Deposition Exhibit well, strike that. Just for the record, it was produced on	6 7 8 9 10 11 12	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is
7 8 9 10 11	materials that was produced about a week ago?  A. Yeah. Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?	6 7 8 9 10 11	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your
7 8 9 10 11 12	materials that was produced about a week ago?  A. Yeah. Q. And that is Deposition Exhibit well, strike that. Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I	6 7 8 9 10 11 12	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have
7 8 9 10 11 12	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed	6 7 8 9 10 11 12 13	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your
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7 8 9 10 11 12 13 14	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.	6 7 8 9 10 11 12 13 14 15	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?  A. Yes.  Q. Does that report, Exhibit 2, and also
7 8 9 10 11 12 13 14 15 16 17	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.  Q. Anything else that you have responsive	6 7 8 9 10 11 12 13 14 15	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?  A. Yes.  Q. Does that report, Exhibit 2, and also marked as Exhibit 10, contain all of the opinions
7 8 9 10 11 12 13 14 15 16 17 18	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.  Q. Anything else that you have responsive to the deposition notice that we have not marked?	6 7 8 9 10 11 12 13 14 15 16 17 18	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?  A. Yes.  Q. Does that report, Exhibit 2, and also marked as Exhibit 10, contain all of the opinions that you intend to offer at any trial or hearing
7 8 9 10 11 12 13 14 15 16 17 18 19 20	materials that was produced about a week ago?  A. Yeah. Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.  Q. Anything else that you have responsive to the deposition notice that we have not marked?  A. Give me a second. Let me read.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?  A. Yes.  Q. Does that report, Exhibit 2, and also marked as Exhibit 10, contain all of the opinions that you intend to offer at any trial or hearing in this matter?
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	materials that was produced about a week ago?  A. Yeah. Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.  Q. Anything else that you have responsive to the deposition notice that we have not marked?  A. Give me a second. Let me read.  MS. PARFITT: If we can go off the	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?  A. Yes.  Q. Does that report, Exhibit 2, and also marked as Exhibit 10, contain all of the opinions that you intend to offer at any trial or hearing in this matter?  A. Well, I mean, it's hard to say it
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.  Q. Anything else that you have responsive to the deposition notice that we have not marked?  A. Give me a second. Let me read.  MS. PARFITT: If we can go off the stenographic record for one moment while he's	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?  A. Yes.  Q. Does that report, Exhibit 2, and also marked as Exhibit 10, contain all of the opinions that you intend to offer at any trial or hearing in this matter?  A. Well, I mean, it's hard to say it contains all the opinions because there have been
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.  Q. Anything else that you have responsive to the deposition notice that we have not marked?  A. Give me a second. Let me read.  MS. PARFITT: If we can go off the stenographic record for one moment while he's doing it.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?  A. Yes.  Q. Does that report, Exhibit 2, and also marked as Exhibit 10, contain all of the opinions that you intend to offer at any trial or hearing in this matter?  A. Well, I mean, it's hard to say it contains all the opinions because there have been some updates since then and, you know, science
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	materials that was produced about a week ago?  A. Yeah.  Q. And that is Deposition Exhibit well, strike that.  Just for the record, it was produced on January 13th of 2019. The updated materials that you have reviewed are listed on Deposition Exhibit 6; is that right?  A. I have not reviewed these materials. I was provided these materials. I have reviewed portions of these. I have not had a chance to review all of these materials.  Q. Anything else that you have responsive to the deposition notice that we have not marked?  A. Give me a second. Let me read.  MS. PARFITT: If we can go off the stenographic record for one moment while he's	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	tell me if you were getting confused.  We have marked Deposition Exhibit 10, which contains all of the attachments  A. Okay.  Q that we have separately marked; is that right?  A. Yeah. Yeah.  Q. All right. The substance of your report in terms of your written opinions, we have marked separately as Exhibit 2; correct?  A. Yes.  Q. Does that report, Exhibit 2, and also marked as Exhibit 10, contain all of the opinions that you intend to offer at any trial or hearing in this matter?  A. Well, I mean, it's hard to say it contains all the opinions because there have been

8 (Pages 26 to 29)

	Page 30		Page 32
1	A. Science evolves, and, you know, we	1	that you intend to provide at any hearing or
2	update our opinions. So it's not like you offer	2	trial in this matter?
3	an updated opinion one day and that stays that	3	A. No. I'm relying on additional evidence
4	way.	4	since then that has become available on this.
5	Q. Dr. Singh, this is our opportunity to	5	Q. Let's I will ask you a new question.
6	ask you questions about the opinions that you	6	Are all of the materials that you are
7	have formed in this matter.	7	relying on in forming the opinions that you
8	As of today, does your report, which we've	8	expect to testify to at any hearing or trial,
9	marked as Exhibit 2 and also	9	identified either in your report, which we have
10	MS. PARFITT: 10.	10	marked as Exhibit 10, or the updated list of
11	Q Exhibit 10, does that include all	11	materials, which we have marked as Exhibit 6?
12	of the opinions that you intend to testify to at	12	A. Yes.
13	any trial or hearing of this matter?	13	MS. PARFITT: And 5.
14	A. Yes. In terms of the causation	14	THE WITNESS: Okay. That's the part of
15	opinions, it does. But in terms of what	15	the whole report.
16	additional evidence has been reviewed or what	16	MR. ZELLERS: Yes.
17	additional evidence has come up that, you know,	17	BY MR. ZELLERS:
18	supports or refutes that, that might have	18	Q. Exhibit 5 had previously been produced
19	changed.	19	as part of your report; is that right?
20	Q. Dr. Singh, do you have any new or	20	A. Yes.
21	additional opinions today that you intend to	21	Q. Is your report accurate?
22	offer at any trial or hearing of this matter	22	A. Yes.
23	beyond the opinions that are included in your	23	Q. Is your report complete?
24	report which we've marked as Exhibit 2 and	24	A. Yes, it is. It has some typos, but
25	Exhibit 10?	25	Q. As we go along, if there's a typo
	Page 31		Page 33
1	A. I'm sorry. I'm just not it's not	1	strike that.
2	like I don't want to answer. I'm trying to	2	Are there any typos that are substantive
3			
	understand. When you say "additional opinions,"	3	typos?
4	does it just mean like a causal opinion or does	3 4	typos?  A. No. But sometimes it's we and they. I
4 5			• •
	does it just mean like a causal opinion or does	4	A. No. But sometimes it's we and they. I
5	does it just mean like a causal opinion or does it mean	4 5	A. No. But sometimes it's we and they. I can point that out at some point in time.
5 6	does it just mean like a causal opinion or does it mean Q. Dr. Singh, you have done this before;	4 5 6	A. No. But sometimes it's we and they. I can point that out at some point in time.  Q. Are there any documents that were in
5 6 7	does it just mean like a causal opinion or does it mean Q. Dr. Singh, you have done this before; right?	4 5 6 7	A. No. But sometimes it's we and they. I can point that out at some point in time.  Q. Are there any documents that were in your possession that you produced to counsel
5 6 7 8	does it just mean like a causal opinion or does it mean Q. Dr. Singh, you have done this before; right? A. Yeah. I'm trying to understand and I'm	4 5 6 7 8	A. No. But sometimes it's we and they. I can point that out at some point in time.  Q. Are there any documents that were in your possession that you produced to counsel responsive to the deposition notice that have not
5 6 7 8 9	does it just mean like a causal opinion or does it mean Q. Dr. Singh, you have done this before; right? A. Yeah. I'm trying to understand and I'm trying to be responsive.	4 5 6 7 8 9	A. No. But sometimes it's we and they. I can point that out at some point in time.  Q. Are there any documents that were in your possession that you produced to counsel responsive to the deposition notice that have not been produced here?
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	does it just mean like a causal opinion or does it mean Q. Dr. Singh, you have done this before; right? A. Yeah. I'm trying to understand and I'm trying to be responsive. Q. This is the defense opportunity to ask you what opinions you intend to offer at any hearing or trial of this matter. As of today, do you have any additional opinions beyond the opinions that are set forth in your report which you intend to offer at any trial or hearing of this matter? A. I don't yeah I mean, it's, you know, the opinions that I've offered are included in the report. Q. Does your report identify and by "report," we can refer to the report that we've	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. No. But sometimes it's we and they. I can point that out at some point in time.  Q. Are there any documents that were in your possession that you produced to counsel responsive to the deposition notice that have not been produced here?  A. No. Not that I can think of.  Q. When were you first contacted by anyone regarding the talc ovarian cancer litigation?  A. So this was in 2017 by Attorney John Restaino and Attorney Parfitt. I don't know the exact day, but it has to be the, you know, spring or summer of 2017. Spring or summer.  Q. Your invoice, your first invoice is dated July of 2017; is that right?  A. Yeah. But, you know, it just covers a period of background. It's not that they contacted me and may have contacted me prior to
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	does it just mean like a causal opinion or does it mean Q. Dr. Singh, you have done this before; right? A. Yeah. I'm trying to understand and I'm trying to be responsive. Q. This is the defense opportunity to ask you what opinions you intend to offer at any hearing or trial of this matter. As of today, do you have any additional opinions beyond the opinions that are set forth in your report which you intend to offer at any trial or hearing of this matter? A. I don't yeah I mean, it's, you know, the opinions that I've offered are included in the report. Q. Does your report identify and by "report," we can refer to the report that we've marked as Exhibit 10.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. No. But sometimes it's we and they. I can point that out at some point in time.  Q. Are there any documents that were in your possession that you produced to counsel responsive to the deposition notice that have not been produced here?  A. No. Not that I can think of.  Q. When were you first contacted by anyone regarding the talc ovarian cancer litigation?  A. So this was in 2017 by Attorney John Restaino and Attorney Parfitt. I don't know the exact day, but it has to be the, you know, spring or summer of 2017. Spring or summer.  Q. Your invoice, your first invoice is dated July of 2017; is that right?  A. Yeah. But, you know, it just covers a period of background. It's not that they contacted me and may have contacted me prior to that.

9 (Pages 30 to 33)

	Page 34		Page 36
1	A. Yes.	1	you asked to do?
2	Q. Anyone else?	2	A. So to clarify, I don't know I was
3	A. No.	3	retained at that time.
4	Q. What attorneys have you met with or	4	I was asked to consult on and provide, you
5	communicated with in the talc ovarian cancer	5	know, a review and look at look at the
6	litigation other than Ms. Parfitt and	6	literature on this topic. So I'm not sure
7	Mr. Restaino?	7	depending on semantics, you can define it as
8	A. So Attorney Chris Tisi, and then I have	8	being retained or, you know I don't think we
9	communicated on the phone with Attorney Gates.	9	had an "agreement," but I was asked to provide a
10	Is that no. Margaret?	10	consultation on that matter. And these invoices
11	Q. Margaret Thompson?	11	include that consult.
12	A. Thompson. Yeah.	12	Q. In the first part of 2017, what were
13	Q. Do you know Margaret Thompson?	13	you asked by counsel for plaintiffs in the talc
14	A. I mean, I know her as an attorney. I	14	litigation, ovarian cancer talc litigation, to
15	just spoke to her on the phone for 30 minutes.	15	do?
16	Q. Have you ever met in person with	16	MS. PARFITT: Objection. Limit your
17	Ms. Thompson?	17	response to communications with regard to simply
18	A. No.	18	the requests, not the conversations.
19	Q. Have you ever had any communications or	19	A. Yeah. So I was asked to review, you
20	interactions with Ms. Thompson other than the	20	know, the literature on talcum powder products
21	30-minute-or-so phone call?	21	and ovarian cancer.
22	A. No.	22	Q. Had you ever done that before?
23	Q. When was that conversation with	23	MS. PARFITT: Objection. Form.
24	Ms. Thompson?	24	A. I mean, when I say "review," yes, I had
25	A. I don't know. A couple of days ago.	25	read about talcum powder products and ovarian
	Page 35		Page 37
1	Yeah.	1	cancer.
2	Q. It was in preparation for the	2	Q. You were asked to make a systematic
3			Q. Tou were asked to make a systematic
	deposition; is that right?	3	review of the literature relating to talcum
4		3 4	
	deposition; is that right?		review of the literature relating to talcum
4	deposition; is that right?  A. Yes.	4	review of the literature relating to talcum powder products and ovarian cancer; is that
4 5	deposition; is that right?  A. Yes.  Q. How much time did you spend with the	4 5	review of the literature relating to talcum powder products and ovarian cancer; is that right?
4 5 6	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this	4 5 6	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review,
4 5 6 7	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?	4 5 6 7 8 9	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different
4 5 6 7 8	deposition; is that right?  A. Yes. Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah,	4 5 6 7 8	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review
4 5 6 7 8 9	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours.  But, again, I can't be very precise.  Q. Any other attorneys that you've	4 5 6 7 8 9 10 11	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different
4 5 6 7 8 9 10 11	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours.  But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to	4 5 6 7 8 9 10 11	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review
4 5 6 7 8 9 10	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours.  But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys	4 5 6 7 8 9 10 11 12	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained,
4 5 6 7 8 9 10 11	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours.  But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to	4 5 6 7 8 9 10 11	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.
4 5 6 7 8 9 10 11 12	deposition; is that right?  A. Yes. Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise. Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.	4 5 6 7 8 9 10 11 12 13 14 15	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes.
4 5 6 7 8 9 10 11 12 13	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.  Q. Do you understand that you are or	4 5 6 7 8 9 10 11 12 13 14 15	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes. Q to work with the attorneys for
4 5 6 7 8 9 10 11 12 13 14 15	deposition; is that right?  A. Yes. Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise. Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.	4 5 6 7 8 9 10 11 12 13 14 15	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.  Q. Do you understand that you are or strike that have been retained as an expert by plaintiffs in the MDL talc ovarian cancer	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes. Q to work with the attorneys for plaintiffs; is that right? A. Yes.
4 5 6 7 8 9 10 11 12 13 14 15 16 17	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.  Q. Do you understand that you are or strike that have been retained as an expert by	4 5 6 7 8 9 10 11 12 13 14 15 16	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes. Q to work with the attorneys for plaintiffs; is that right? A. Yes. MS. PARFITT: Objection. Form.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.  Q. Do you understand that you are or strike that have been retained as an expert by plaintiffs in the MDL talc ovarian cancer	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes. Q to work with the attorneys for plaintiffs; is that right? A. Yes. MS. PARFITT: Objection. Form. Q. Were you ever given any new or
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours.  But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.  Q. Do you understand that you are or strike that have been retained as an expert by plaintiffs in the MDL talc ovarian cancer litigation?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes. Q to work with the attorneys for plaintiffs; is that right? A. Yes. MS. PARFITT: Objection. Form. Q. Were you ever given any new or additional assignment in the MDL talc ovarian
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours.  But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.  Q. Do you understand that you are or strike that have been retained as an expert by plaintiffs in the MDL talc ovarian cancer litigation?  A. Right now, I do. Yes.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes. Q to work with the attorneys for plaintiffs; is that right? A. Yes. MS. PARFITT: Objection. Form. Q. Were you ever given any new or
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.  Q. Do you understand that you are or strike that have been retained as an expert by plaintiffs in the MDL talc ovarian cancer litigation?  A. Right now, I do. Yes.  Q. Is there any other ovarian cancer litigation matter that you have been retained in?  A. No.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes. Q to work with the attorneys for plaintiffs; is that right? A. Yes. MS. PARFITT: Objection. Form. Q. Were you ever given any new or additional assignment in the MDL talc ovarian
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	deposition; is that right?  A. Yes.  Q. How much time did you spend with the lawyers for plaintiffs preparing for this deposition?  A. With the lawyers, I've spent yeah, I'd have to go back, maybe five or six hours. But, again, I can't be very precise.  Q. Any other attorneys that you've communicated with that you understand to represent the plaintiffs other than the attorneys that you have identified?  A. No. Not that I can recall.  Q. Do you understand that you are or strike that have been retained as an expert by plaintiffs in the MDL talc ovarian cancer litigation?  A. Right now, I do. Yes.  Q. Is there any other ovarian cancer litigation matter that you have been retained in?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	review of the literature relating to talcum powder products and ovarian cancer; is that right?  A. Not necessarily a systematic review, but they asked me to, you know, review the literature, and I had been reading it from other from my own reading in different journals, and they asked me to, you know, review and, you know, provide my own opinion on that matter.  Q. At some point, you were retained, agreed A. Yes. Q to work with the attorneys for plaintiffs; is that right? A. Yes. MS. PARFITT: Objection. Form. Q. Were you ever given any new or additional assignment in the MDL talc ovarian cancer litigation other than to do a literature

10 (Pages 34 to 37)

	Page 38		Page 40
1	asking the causal question that is the use of	1	that right?
2	talcum powder products a cause of ovarian cancer.	2	A. Yes.
3	Q. You looked at the literature	3	Q. How much are you charging per hour for
4	A. Mm-hmm.	4	your time in this case?
5	Q to try to determine if you could	5	A. \$600 an hour.
6	answer that question; is that right?	6	Q. You have invoices in front of you.
7	A. Yeah. So we looked at I looked at	7	What is the total value of the time that
8	the literature and, you know, obviously, looked	8	you've spent on the talc ovarian cancer
9	at other documents and performed a methodology,	9	litigation, whether that's been billed or not
10	and we can discuss that in detail later.	10	billed, paid or not paid?
11	But the primary question of interest is	11	A. I can't calculate the time. I can
12	was, is the use of perineal use of talcum powder	12	calculate
13	products associated with and causally related to	13	Q. Can you estimate it for us?
14	the development of ovarian cancer.	14	A. I don't want to give a number that's
15	Q. That has been the request from	15	inaccurate; right? I mean, these are accurate
16	plaintiffs' counsel to you in terms of providing	16	numbers. But I will just have to sum it up
17	expert opinions in this matter; is that right?	17	Q. Let's try to do this as quickly as we
18	A. Yes.	18	can.
19	Q. When were you first asked to prepare a	19	A. Yeah.
20	report setting forth your opinions?	20	Q. The five invoices that you've marked
21	A. Again, I can't recall the specific	21	or strike that that we have marked as
22	timelines. I'm sorry. It's been a while.	22	Deposition Exhibit 13
23	Q. Were you asked by plaintiffs to assume	23	A. Mm-hmm.
24	any facts?	24	Q does that capture all of your time
25	A. No. I mean, at that time, you know,	25	on the ovarian cancer talc litigation through
	Page 39		Page 41
1	and even prior to that, I was reading the	1	November of last year?
2	literature. I was, you know, agnostic to it.	2	A. Yes.
3	And, yeah, I didn't in fact, I didn't	3	Q. Is there any additional time that you
4	form an opinion on this topic until until the	4	have spent on the talcum powder litigation up
5	very end of, you know, 2018.	5	through November of last year that's not
6	Q. When you say you were "agnostic"	6	reflected in the invoices we've marked as
7	A. Mm-hmm.	7	Exhibit 13?
8	Q to this issue, whether or not	8	A. No.
9	talcum powder products are associated with	9	Q. All right. First invoice, what is the
10	ovarian cancer, do you mean that you had not	10	total?
11	formally come up with or developed any opinions	11	A. 9,300.
12	prior to becoming involved as an expert for	12	Q. The second invoice, total?
13	plaintiffs?	13	A. Twenty, one, zero, zero.
14	MS. PARFITT: Objection. Form.	14	Q. 21,000?
15	A. Yeah. So my what I mean is I had	15	A. 20,100.
16	not systematically reviewed the literature to	16	Q. Next invoice, total?
17	form an opinion whether talcum powder products	17	A. 5,100.
18	is, so I had not done the processes required to,	18	Q. Next invoice, total?
19	you know, develop an opinion.	19	A. 19,200.
20	Q. All right. You have now done that and	20	Q. Last invoice, total?
	you're here to talk about it; is that right?	21	A. 40,800.
21		22	Q. Since November of 2018, can you
22	A. Yes.		
22 23	Q. Plaintiffs' counsel have paid you for	23	estimate for us the number of hours that you have
22			

	Page 42		Page 44
1	hours that I spent with the lawyers, I don't	1	A. Okay.
2	know. Maybe I've spent 10, 15 hours on my own.	2	Q. What percentage of income is from
3	Maybe more. I just don't have that exact number.	3	consulting on litigation matters? Give us an
4	I'll have to look.	4	estimate.
5	Q. At some point, you will submit an	5	A. Okay. Yeah. Maybe 30 percent. I'm
6	invoice	6	doing my best to give you
7	A. Yes.	7	Q. Is that your you're here to be
8	Q for your time; is that right?	8	truthful; correct?
9	A. After today. Yeah.	9	A. Yeah.
10	Q. Have you been disclosed as an expert in	10	Q. Is 30 percent of your income from
11	any other talcum powder proceeding aside from	11	consulting on litigation matters, is that your
12	this case?	12	best estimate as you sit here today?
13	A. No.	13	MS. PARFITT: Objection. Some clarity
14	Q. What percent of your professional time	14	as to over what period of time?
15	do you currently spend performing work as a	15	A. Yeah. Over five years, I mean, that's
16	consultant?	16	my best estimate.
17	A. Yeah. It could be you know, varies.	17	Q. Is it a little bit more now?
18	It could be 20 to 30 percent of my time.	18	MS. PARFITT: Objection.
19	Sometimes 20 percent.	19	A. Well, over the last year, yes, but over
20	Q. Has that 20 to 30 percent of your	20	five.
21	professional time spent working as a consultant,	21	Q. Over the last year, what are you
22	has that been consistent for the past five, ten	22	working on? You're working on the talc
23	years?	23	litigation; is that right?
24	A. Yeah. So, actually, it's been less in	24	MS. PARFITT: Objection. Form.
25	the past, sometimes a little more, but, you know,	25	Q. Doctor, did you hear my question?
			Q. Zooto, ala you nour my queonom
	Page 43		Page 45
1	overall, I would average out, you know, sort of	1	A. Yeah. Yeah.
2	as I was preparing over the last five years, it	2	Q. What other litigations are you serving
3	would probably be 15 to 20 percent, but, you	3	as an expert for?
4	know	4	A. Viagra.
5	Q. Currently, though, best estimate is 20	5	Q. You're an expert for plaintiffs in
6	to 30 percent; is that right?	6	Viagra; is that right?
7	A. Over the last six months. Yes.	7	A. Yes.
8	Q. What percent of your income is from	8	Q. What other litigations are you serving
9	consulting on litigation matters?	9	as an expert for plaintiffs in?
10	A. Again, I can't give you my gross	10	A. None other than that, that I know of.
11	income. I mean, I	11	Q. Are you still working as an expert for
12	Q. I don't want your gross income. I'm	12	plaintiffs in the Lipitor litigation?
13	asking just for I just want to know a	13	A. That ended several years ago, as far as
14	percentage of your income that comes from	14	I recall.
15	consulting in litigation cases.	15	Q. You list two Tasigna cases against
16	A. Well, again, you know, consulting is	16	Novartis.
17	not just litigation for me. As I said, I've	17	Are you still working on those cases?
18	consulted, you know, including for J&J, Eli	18	A. That ended in, I think, in yeah, it
19	Lilly, others, that's, you know, on my CV.	19	ended.
20	Overall, and other, you know, insurers. So it's	20	Q. You list on your expert testimony,
21	not just first of all, it's not litigation	21	2018; is that right?
22	consulting that I do.	22	A. Yes. I mean, but I listed everything
23	Q. Dr. Singh	23	that was I have done in the five years. It
24	A. Yes.	24	doesn't mean that those are ongoing.
		25	Q. You are no longer serving as an expert,
25	A. Yes. Q listen to my question, if you can.	1	

12 (Pages 42 to 45)

	Page 46		Page 48
1	to your knowledge, in the Tasigna cases; is that	1	A. I don't understand. Like, what is a
2	right?	2	personal injury? Is it like somebody MVA kind
3	A. Yes.	3	of case or
4	Q. How about the Rahmoeller versus Walmart	4	Q. Well, you've been involved in Lipitor.
5	litigation, is that still ongoing?	5	You have been involved in a number of other
6	A. That stopped, but, you know, it's been	6	litigations. Let me withdraw that question. Let
7	a year since I've heard anything, so I don't	7	me make it a little more precise.
8	know.	8	Have you ever been retained in a case
9	Q. You also provided testimony in a matter	9	involving cosmetic products?
10	of Brufett versus Washington University.	10	A. No.
11	Is that still ongoing?	11	Q. In the preparation of your report, did
12	A. That has ended.	12	you review the other expert reports provided by
13	Q. Is it fair to say that all of the cases	13	plaintiffs in this MDL litigation?
14	in which you have been retained in the past	14	A. I mean, other than those cited, I have
		15	not had a chance to review them.
15 16	A. Sure.	l .	
16	Q as an expert for plaintiffs	16	Q. The updated materials list that you
17	involving a pharmaceutical company defendant have	17	have produced here today, which we've marked as
18	involved prescription medications?	18	Exhibit 6, it contains a number of expert reports
19	A. Yeah. Prescription medications, issues	19	from plaintiff experts in the MDL talcum powder
20	of systems. I mean, that's my area of research.	20	ovarian cancer litigation; is that right?
21	Q. How much of your work is for plaintiffs	21	A. Yes.
22	versus defense as a litigation consultant?	22	Q. What is Exhibit 6? It says "Updated
23	MS. PARFITT: Objection. Form.	23	materials."
24	A. Yeah. I mean, over the last ten years,	24	Does that mean updated materials that you
25	I've provided opinions to both sides, but I have	25	have reviewed and considered?
	Page 47		Page 49
1	Page 47 not been, you know when you say how much of	1	Page 49  A. They were provided to me at some point
1 2		1 2	
	not been, you know when you say how much of your work, is it time spent or	l .	A. They were provided to me at some point in time between November 15th, and I haven't
2	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your	2	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the
2 3 4	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right?	2 3 4	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been
2 3 4 5	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah.	2 3	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.
2 3 4 5 6	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah. Q. And it can be more than 70 percent; is	2 3 4 5	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.  Q. This list of updated materials is
2 3 4 5 6 7	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah. Q. And it can be more than 70 percent; is that right?	2 3 4 5 6 7	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.  Q. This list of updated materials is something that was provided to you by plaintiffs'
2 3 4 5 6 7 8	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah. Q. And it can be more than 70 percent; is that right? MS. PARFITT: Objection to form.	2 3 4 5 6 7 8	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.  Q. This list of updated materials is something that was provided to you by plaintiffs' counsel; is that right?
2 3 4 5 6 7 8 9	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah. Q. And it can be more than 70 percent; is that right? MS. PARFITT: Objection to form. Objection to form.	2 3 4 5 6 7 8	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.  Q. This list of updated materials is something that was provided to you by plaintiffs' counsel; is that right?  A. Yes.
2 3 4 5 6 7 8 9	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah. Q. And it can be more than 70 percent; is that right? MS. PARFITT: Objection to form. Objection to form. A. Well, it depends, again, for frame of	2 3 4 5 6 7 8 9	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.  Q. This list of updated materials is something that was provided to you by plaintiffs' counsel; is that right?  A. Yes.  Q. Have you reviewed any of the materials
2 3 4 5 6 7 8 9 10	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah. Q. And it can be more than 70 percent; is that right? MS. PARFITT: Objection to form. Objection to form. A. Well, it depends, again, for frame of time and, you know, if you say yes, in the last	2 3 4 5 6 7 8 9 10	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.  Q. This list of updated materials is something that was provided to you by plaintiffs' counsel; is that right?  A. Yes.  Q. Have you reviewed any of the materials that are on the updated materials list, which we
2 3 4 5 6 7 8 9 10 11	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah. Q. And it can be more than 70 percent; is that right? MS. PARFITT: Objection to form. Objection to form. A. Well, it depends, again, for frame of time and, you know, if you say yes, in the last year, yes. More than	2 3 4 5 6 7 8 9 10 11	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.  Q. This list of updated materials is something that was provided to you by plaintiffs' counsel; is that right?  A. Yes.  Q. Have you reviewed any of the materials that are on the updated materials list, which we have marked as Exhibit 6?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	not been, you know when you say how much of your work, is it time spent or Q. In terms of time spent, most of your work is for plaintiffs; is that right? A. I would say, yeah, 70 percent. Yeah. Q. And it can be more than 70 percent; is that right? MS. PARFITT: Objection to form. Objection to form. A. Well, it depends, again, for frame of time and, you know, if you say yes, in the last year, yes. More than Q. Last year, it's been more than 70 percent A. Sure. Q for plaintiffs; is that right? A. Yes. Q. Have you ever been retained in a case involving asbestos? A. No. Q. Have you ever been involved in a case strike that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. They were provided to me at some point in time between November 15th, and I haven't even I have actually not reviewed any of the expert reports other than those that have been cited in my report.  Q. This list of updated materials is something that was provided to you by plaintiffs' counsel; is that right?  A. Yes.  Q. Have you reviewed any of the materials that are on the updated materials list, which we have marked as Exhibit 6?  A. Yeah. I had a chance to review some of them.  Q. Which materials that are identified on Exhibit 6, updated materials, have you actually looked at, reviewed, and considered?  A. Yeah. So, I mean, I was already aware of the Health Canada assessment and, you know, so that's I've reviewed.  I have reviewed, obviously, the Up to Date, that childs sent.

13 (Pages 46 to 49)

	Page 50		Page 52
1	Where is that listed?	1	Q. Did you review Talc Information Sheet,
2	A. No. 2. No. 2.	2	Health Canada?
3	Q. All right. You've reviewed Chen Up to	3	A. Yes.
4	Date. You have reviewed the second reference,	4	Q. Talc Potential Risk of Lung Effects?
5	Committee on the State of Science.	5	A. Yes.
6	A. Yeah.	6	Q. Task Force on Science Risk Assessment?
7	Q. Have you reviewed the Evolving	7	A. Yes.
8	Paradigms and Research and Care?	8	Q. The Weed Reference?
9	A. Yes.	9	A. Yes.
10	Q. The Draft Screening Assessment, Talc	10	Q. And the Zervomanolakis citation?
11	Health Canada?	11	A. Yes.
12	A. Yes.	12	Q. Have we covered all of the materials
13	Q. The EFSA Science Committee?	13	that you've reviewed on the updated materials
14	A. Yes.	14	list? Is that right?
15 16	<ul><li>Q. The EPA documents that are listed?</li><li>A. No.</li></ul>	15	A. Yes.
16 17		16 17	Q. Have you communicated or had any
18	<ul><li>Q. The FDA Ingredients Tale?</li><li>A. No.</li></ul>	18	discussions with any of the other plaintiffs' experts in the talc ovarian cancer litigation?
18 19	A. No. O. The Fadak Burnola citation?	19	A. No.
20	A. Yes.	20	A. No. Q. Have you reviewed any deposition or
21	Q. The Federal Register, Volume 81?	21	trial transcripts from prior talcum powder cases?
22	A. Yes.	22	A. Not prior cases, but I reviewed the
23	Q. Have you reviewed the Kemp hearing	23	deposition of Dr. Plunkett.
24	opinion and order?	24	Q. Plunkett?
25	A. I don't think so.	25	A. Plunkett.
	Page 51		Page 53
1	Q. The Keys Model Information Bias?	1	Q. Have you reviewed any other depositions
2	A. Yes.	2	of experts that have been taken in the MDL
3	Q. Kunz?	3	ovarian cancer talcum powder litigation?
4	A. Yes.	4	A. No.
5	Q. Official Journal of the European Union?	5	Q. Did you conduct any independent
6	A. No.	6	investigation to reach your opinions?
7	Q. Qiao, Q-I-A-O?	7	A. I mean, I my opinion is independent
8	A. No.	8	of these.
_	Q. Risk Management Scope, Talc Health	1	Q. As I understand it, what you did is you were asked by plaintiffs to review and consider
10	Canada?	10	• •
11 12	A. No.	12	and form an opinion regarding the causal question. Is that right?
13	Q. You have not reviewed any of the plaintiff expert reports submitted in this	13	question. Is that right?  A. Yes.
13 14	matter. Is that your testimony?	14	Q. To do that, you went and you reviewed a
15	A. Yeah. They were provided to me and,	15	number of different literature sources; is that
16	you know, I formed my opinion independent of	16	right?
17	them.	17	MS. PARFITT: Objection. Misstates his
ı - '	Q. Have you reviewed any of the reports	18	opinion. He indicated he had reviewed some prior
18	prepared and submitted by plaintiffs that are	19	to that.
18 19	propared and bachines by planting that are	20	MR. ZELLERS: Ms. Parfitt, just object,
19	identified in your undated materials?	U	
19 20	identified in your updated materials?  A. No. Except if any of them were cited.	1	form. And let's not have speaking objections
19 20 21	A. No. Except if any of them were cited,	21 22	form. And let's not have speaking objections.  MS. PARFITT: And you won't find that I
19 20	A. No. Except if any of them were cited, that's the one that I reviewed it in.	21 22	MS. PARFITT: And you won't find that I
19 20 21 22	<ul><li>A. No. Except if any of them were cited, that's the one that I reviewed it in.</li><li>Q. Yup. Did you review Talc Canada Plain</li></ul>	21	
19 20 21 22 23	A. No. Except if any of them were cited, that's the one that I reviewed it in.	21 22 23	MS. PARFITT: And you won't find that I will. I want to make sure we have an accurate

14 (Pages 50 to 53)

	Page 54		Page 56
1	recross, but I'm trying to clean it up.	1	not necessarily the ones who may have helped me
2	BY MR. ZELLERS:	2	in printing articles.
3	Q. Doctor, go ahead.	3	Q. My question is: Who helped prepare
4	A. I didn't get the question. Can you	4	your report other than yourself?
5	repeat?	5	MS. PARFITT: Objection. Objection. I
6	Q. Sure. The question is: You were asked	6	believe you've asked that. He's answered it.
7	to form an opinion by plaintiffs. You went out	7	A. Okay. Let me answer.
8	and you reviewed the literature.	8	Q. Sure. Go ahead, Doctor. Please
9	You considered the literature and you	9	answer.
10	formulated an opinion; is that right?	10	A. I prepared my report.
11	A. Yes.	11	Q. I understand you prepared your report.
12	MS. PARFITT: Objection.	12	My question is: Did anyone assist you in
13	A. And it was an independent opinion.	13	preparing your report?
14	Q. An independent opinion based upon your	14	MS. PARFITT: Objection.
15	review of the literature; is that right?	15	A. No.
16	A. Yeah. Based upon my review of the	16	Q. You were provided some materials by
17	literature and the documents and, you know,	17	plaintiffs' counsel; is that right?
18	whatever was available to me.	18	A. Yes.
19	Q. And those all of those materials	19	Q. You reviewed some of those materials,
20	that you reviewed, considered and relied upon	20	but not all of those materials; is that right?
21	have been included in the exhibits that we've	21	A. Yes.
22	marked in this deposition; is that right?	22	Q. In terms of the references, Exhibit 4.
23	A. That is correct.	23	And that is identified as Pages 67 through 75 in
24	Q. Was there anything that you asked	24	your full report that we marked as Exhibit 10.
25	plaintiffs' counsel for to prepare your report	25	But looking at your references, Exhibit 4,
	Page 55		Page 57
1	that you were not provided with?	1	some of these references were provided by counsel
2	A. No.	2	for plaintiffs to you; is that right?
3	Q. Did anyone assist you in the	3	MS. PARFITT: Objection.
4	preparation of your report?	4	A. Yes.
		T	
5	A. Well, I may have asked them to print,	5	Q. Some, you went out and found on your
5 6	A. Well, I may have asked them to print, like, these things and, you know, I may have		Q. Some, you went out and found on your own; is that right?
	A. Well, I may have asked them to print,	5	<ul><li>Q. Some, you went out and found on your own; is that right?</li><li>A. Well, it's not that way. It's the</li></ul>
6	A. Well, I may have asked them to print, like, these things and, you know, I may have	5 6 7 8	<ul><li>Q. Some, you went out and found on your own; is that right?</li><li>A. Well, it's not that way. It's the majority of the references, I would say</li></ul>
6 7	A. Well, I may have asked them to print, like, these things and, you know, I may have asked my I had means to print some articles	5 6 7 8 9	Q. Some, you went out and found on your own; is that right?  A. Well, it's not that way. It's the majority of the references, I would say 95 percent of, are my own work, and, you know, I
6 7 8	A. Well, I may have asked them to print, like, these things and, you know, I may have asked my I had means to print some articles when I was preparing that.	5 6 7 8	Q. Some, you went out and found on your own; is that right?  A. Well, it's not that way. It's the majority of the references, I would say 95 percent of, are my own work, and, you know, I had questions about the product and the
6 7 8 9	A. Well, I may have asked them to print, like, these things and, you know, I may have asked my I had means to print some articles when I was preparing that.  Q. Do you have a staff?  A. Yes.  Q. All right. Who is your staff?	5 6 7 8 9	Q. Some, you went out and found on your own; is that right?  A. Well, it's not that way. It's the majority of the references, I would say 95 percent of, are my own work, and, you know, I
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6 7 8 9 10 11 12 13	A. Well, I may have asked them to print, like, these things and, you know, I may have asked my I had means to print some articles when I was preparing that.  Q. Do you have a staff?  A. Yes.  Q. All right. Who is your staff?  A. I have several staff. I have, you know, three offices.	5 6 7 8 9 10 11 12 13	Q. Some, you went out and found on your own; is that right?  A. Well, it's not that way. It's the majority of the references, I would say 95 percent of, are my own work, and, you know, I had questions about the product and the mechanism, what additional documents were available.  And that's a process. And documents were
6 7 8 9 10 11 12 13	A. Well, I may have asked them to print, like, these things and, you know, I may have asked my I had means to print some articles when I was preparing that.  Q. Do you have a staff?  A. Yes.  Q. All right. Who is your staff?  A. I have several staff. I have, you know, three offices.  Q. So you have three offices?	5 6 7 8 9 10 11 12 13	Q. Some, you went out and found on your own; is that right?  A. Well, it's not that way. It's the majority of the references, I would say 95 percent of, are my own work, and, you know, I had questions about the product and the mechanism, what additional documents were available.  And that's a process. And documents were provided, and they need to be cited and are
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15 (Pages 54 to 57)

	Page 58		Page 60
1	respect to the additional materials and data	1	additional materials and data considered, items
2	considered, Exhibit 5.	2	that are listed in Exhibit 5?
3	Do you see that?	3	A. By reviewed and considered, I mean,
4	A. Yes.	4	have I read every word of it? No. I reviewed
5	Q. What's the difference between	5	and considered.
6	Exhibit 4, references, and Exhibit 5, additional	6	Q. Who prepared the additional materials
7	materials and data considered?	7	and data considered list?
8	A. So as I went about and did my, you	8	MS. PARFITT: Objection.
9	know, systematic review and, you know, umbrella	9	A. I prepared the list, but I asked them
10	review, I gathered all the materials and, you	10	also to help me with what materials they had
11	know, I included studies and data that provided	11	sent.
12	original data on the causal question that we	12	Q. The lawyers for plaintiffs; is that
13	discussed.	13	right?
14	Q. Doctor, my question was simply, what's	14	A. Yes.
15	the difference between references and additional	15	Q. So in your documents, you do have a
16	materials and data considered?	16	listing of the materials that were provided to
17	A. So the additional materials are those	17	you by plaintiffs' counsel for consideration; is
18	that were, I would say, you know, reviewed, were	18	that right?
19	still reviewed in forming the opinion, but they	19	MR. LOCKE: Objection. Misstates the
20	are not they don't they don't form the	20	testimony.
21	basis of my opinion.	21	A. I'm sorry. Can you repeat?
22	Q. The materials that you relied on in	22	Q. Sure. The question is: You do have,
23	forming your opinion are what you've set forth as	23	because you requested it, a listing of the
24	your references, Exhibit 4; is that right?	24	documents and materials that were provided to you
25	MS. PARFITT: Objection.	25	by plaintiffs' counsel for you to consider;
	Page 59		Page 61
1	Page 59  A. Yeah. I mean, and then things that,	1	Page 61 correct?
1 2		1 2	correct?
	A. Yeah. I mean, and then things that,	l .	
2	A. Yeah. I mean, and then things that, you know obviously, for the report, it is the	2	correct?  MS. PARFITT: Objection. Misstates his
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	Page 62		Page 64
1	request?	1	material, I can tell you, there's not enough time
2	A. I requested additional materials	2	to review all of it. I mean, if somebody has,
3	regarding what are the constituents of talcum	3	that's great. I can't.
4	powder products. I you know, additional	4	Q. Are you done?
5	materials regarding testing of talcum powder	5	A. Yes.
6	products I you know, anything to, you know,	6	Q. Did you, when you made that request,
7	enhance my understanding whether there's evidence	7	intend for plaintiffs to provide you with all of
8	to support or refute what we are seeing in the	8	the information that was available related to
9	epidemiologic studies about an increased risk of	9	testing or related to ingredients or whatever
10	ovarian cancer with talcum powder products.	10	other issues you requested documents on?
11	Q. When you requested these materials,	11	MS. PARFITT: Objection. Form.
12	testing materials, ingredient materials and any	12	A. Yes.
13	other materials, did you want to see all of the	13	Q. All right. In your report, you cite
14	materials that were available so that you could	14	and this is in references to the depositions
15	form your opinion?	15	of witnesses in the talcum powder litigation.
16	MS. PARFITT: Objection. Form.	16	For example, and let's take a look at Exhibit 4,
17	A. All is you know, there's only so	17	your references, Cite No. 4 is to the deposition
18	many hours. I mean, you know, I think I wanted	18	of Linda Loretz.
19	to see as much as, you know, was relevant to	19	Did you review this?
20	forming an opinion.	20	A. Yes, I did.
21	Q. Well, you asked for records of testing	21	Q. And who is she?
22	and you were provided with records, and we'll	22	A. I don't recall offhand, who she is.
23	take a look at it	23	Q. Is that information that was provided
24	A. Sure.	24	to you by plaintiffs' counsel?
25	Q that purport to show that there is	25	A. Yes.
	Page 63		Page 65
1	asbestos or asbestos has been found in talcum	1	Q. Who is Joshua Muscat, reference list,
2	powder; correct?	2	Cite No. 5?
3	A. I mean, that's not the only that's	3	A. I think he did one of the
4	not only	4	meta-analyses. He's an author of one of the
5	Q. Understood.	5	meta-analyses as well.
6	MS. PARFITT: Excuse me. Let him		meta-anaryses as wen.
	MS. FARTIT. Excuse me. Let mm	6	Q. Who is Alice Blount, Cite 27?
7	finish his answer, if you will, please. I'm not	6 7	
7 8			Q. Who is Alice Blount, Cite 27?
	finish his answer, if you will, please. I'm not	7	<ul><li>Q. Who is Alice Blount, Cite 27?</li><li>A. Yeah. They did a study on talc and</li></ul>
8	finish his answer, if you will, please. I'm not sure he was done. Appreciate that.	7 8	<ul><li>Q. Who is Alice Blount, Cite 27?</li><li>A. Yeah. They did a study on talc and also I was deposed on that.</li></ul>
8 9	finish his answer, if you will, please. I'm not sure he was done. Appreciate that.  Q. Are you done?	7 8 9 10 11	<ul> <li>Q. Who is Alice Blount, Cite 27?</li> <li>A. Yeah. They did a study on talc and also I was deposed on that.</li> <li>Q. Did you request that deposition or was that provided to you?</li> <li>MS. PARFITT: Objection.</li> </ul>
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17 (Pages 62 to 65)

	Page 66		Page 68
1	don't	1	A. So we can we can go back to the
2	Q. Can you not answer that question?	2	sections where I cite these and then we can
3	MS. PARFITT: Objection. I believe	3	discuss. Is that okay?
4	A. I'm answering your question.	4	Q. No. Well, and if you need to if you
5	MS. PARFITT: he did.	5	can't answer a question, tell me you can't answer
6	Q. My question is: When you requested	6	a question.
7	documents from plaintiffs' counsel on various	7	My question is: For these five or six folks
8	topics, did you expect to receive whatever	8	who you have quoted a snippet from their
9	documents may support plaintiffs' position and	9	deposition, did you review their entire
10	whatever documents may refute plaintiffs'	10	transcript or did you just review an excerpt?
11	position?	11	MS. PARFITT: Objection to the form.
12	A. Yes.	12	A. So the answer will be, we have to go
13	Q. All right. Who is John Hopkins,	13	one by one.
14	reference item strike that reference list,	14	Q. All right. For Mr. Hopkins, did you
15	Cite 33?	15	review his entire deposition?
16	A. I think it's yeah. It's a	16	A. No.
17	deposition on behalf of J&J, I think.	17	Q. For Ms. Pier, did you review her entire
18	Q. Do you know who Mr. Hopkins is?	18	deposition?
19	A. No, I don't.	19	A. No.
20	Q. Do you know what role he had with	20	Q. For Ms. Blount, did you review her
21	talcum powder?	21	entire deposition?
22	MS. PARFITT: Objection. Form.	22	A. I recall, yes.
23	A. I mean, he was deposed in this	23	Q. Yes, you did?
24	litigation and he provided testimony.	24	A. Yes.
25	Q. The question is: Do you know what role	25	Q. For Ms. Loretz, did you review her
	Page 67		Dago 60
			Page 69
1	Mr. Hopkins played in and with talcum powder?	1	
1 2	Mr. Hopkins played in and with talcum powder?  A. He was providing testimony on behalf of	1 2	entire deposition? A. Yes.
	A. He was providing testimony on behalf of		entire deposition?
2	A. He was providing testimony on behalf of the company. Is that	2	entire deposition? A. Yes.
2	A. He was providing testimony on behalf of the company. Is that Q. Other than that, do you know anything	2 3	entire deposition? A. Yes. Q. Did strike that.
2 3 4	A. He was providing testimony on behalf of the company. Is that	2 3 4	entire deposition? A. Yes. Q. Did strike that. For Mr. Muscat, did you review his entire
2 3 4 5	A. He was providing testimony on behalf of the company. Is that Q. Other than that, do you know anything about what he did on behalf of the company?	2 3 4 5	entire deposition? A. Yes. Q. Did strike that. For Mr. Muscat, did you review his entire deposition?
2 3 4 5 6	A. He was providing testimony on behalf of the company. Is that Q. Other than that, do you know anything about what he did on behalf of the company? A. No.	2 3 4 5 6	entire deposition?  A. Yes. Q. Did strike that. For Mr. Muscat, did you review his entire deposition?  A. Yes, I did.
2 3 4 5 6 7	<ul> <li>A. He was providing testimony on behalf of the company. Is that</li> <li>Q. Other than that, do you know anything about what he did on behalf of the company?</li> <li>A. No.</li> <li>Q. Do you know what his positions were?</li> </ul>	2 3 4 5 6 7	entire deposition?  A. Yes. Q. Did strike that. For Mr. Muscat, did you review his entire deposition?  A. Yes, I did. Q. Did you review all of the exhibits to
2 3 4 5 6 7 8	<ul> <li>A. He was providing testimony on behalf of the company. Is that</li> <li>Q. Other than that, do you know anything about what he did on behalf of the company?</li> <li>A. No.</li> <li>Q. Do you know what his positions were?</li> <li>A. I don't recall.</li> </ul>	2 3 4 5 6 7 8	entire deposition?  A. Yes. Q. Did strike that. For Mr. Muscat, did you review his entire deposition?  A. Yes, I did. Q. Did you review all of the exhibits to those depositions?
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18 (Pages 66 to 69)

	Page 70		Page 72
1	as those conducted by, you know, Health Canada.	1	as humanly possible.
2	I mean, they clearly state that, you know,	2	Q. My question is a little more specific.
3	you gather all relevant available evidence.	3	I'm talking now just about any documents produced
4	Q. That was your goal; is that right?	4	by Johnson & Johnson defendants or any documents
5	A. Yes.	5	produced by Imerys defendants.
6	Q. Did Health Canada review deposition	6	You do cite to several of those in your
7	testimony of company witnesses, to your	7	reference list; correct?
8	knowledge?	8	A. Yes.
9	A. Well, they were not available to them.	9	Q. You were provided those documents by
10	Q. When you practice, outside of being a	10	counsel for plaintiffs; correct?
11	litigation consultant, do you rely on excerpts of	11	A. Yes.
12	deposition testimony?	12	Q. Were you provided a large set of
13	A. Well, again, you know, outside of this,	13	materials, company documents from the J&J
14	when I do papers I mean, I do include	14	defendants and from the Imerys defendants, or
15	unpublished or whatever you can collect,	15	were you provided with select documents?
16	whether whether it's excerpts of I mean, I	16	MS. PARFITT: Objection. Form.
17	haven't if I look at my past papers, I can't	17	A. I mean, these are company documents. I
18	say that I've used excerpts of deposition		mean, what is the difference between the two?
19	transcripts.	18 19	
20	Q. Did strike that.		Like explain to me by example.
21	You also cite company documents in your list	20	Q. Were you provided a box of J&J
22	of references; is that right?	21	documents or documents produced by J&J for your
23	A. Which one is that?	22	review by plaintiffs' counsel?
24		23	MS. PARFITT: Objection. Form.
	Q. Exhibit 4.	24	A. I don't know. I mean, they provided
25	A. Which company?	25	documents. I see them as documents. I don't see
	Page 71		Page 73
1	Q. Well, for example, Item 116 refers to	1	a difference between. You can you know, you
2	an Imerys document, item 63 refers to a document	2	can make that connection.
3	or set of documents produced by the	3	Q. Let me do it this way.
4	Johnson & Johnson defendants; correct?	4	A. Sure.
5	A. What was the second one? I'm sorry.	5	Q. Are the documents that you reviewed
6	You said 116 and then?	6	relating to those produced by J&J or produced by
7	Q. Yes. Sixty	7	Imerys, do you list those in your references,
8	MS. PARFITT: 63.	8	Exhibit 4, and your additional materials and data
9	Q. 63.	9	considered, Exhibit 5?
	A. I'll have to go back and see what do	10	A. They are listed. Yes.
10		1	•
10 11		11	Q. All right. When you are doing your day
	they cite about, to refresh my memory.	11 12	Q. All right. When you are doing your day job, outside of your litigation consulting work,
11	they cite about, to refresh my memory.  Q. As you sit here, you don't remember		job, outside of your litigation consulting work,
11 12	they cite about, to refresh my memory.  Q. As you sit here, you don't remember what those documents are, do you?	12	job, outside of your litigation consulting work, do you rely on internal company documents?
11 12 13	they cite about, to refresh my memory.  Q. As you sit here, you don't remember what those documents are, do you?  A. Yeah. Yeah. I'd have to go back.	12 13 14	job, outside of your litigation consulting work, do you rely on internal company documents? MS. PARFITT: Objection. Form.
11 12 13 14	they cite about, to refresh my memory.  Q. As you sit here, you don't remember what those documents are, do you?  A. Yeah. Yeah. I'd have to go back.  Q. Is that correct?	12 13 14 15	job, outside of your litigation consulting work, do you rely on internal company documents? MS. PARFITT: Objection. Form. A. I mean, I have relied on company
11 12 13 14 15	they cite about, to refresh my memory.  Q. As you sit here, you don't remember what those documents are, do you?  A. Yeah. Yeah. I'd have to go back.  Q. Is that correct?  A. Yeah. I mean, I have to go back to my	12 13 14 15 16	job, outside of your litigation consulting work, do you rely on internal company documents?  MS. PARFITT: Objection. Form.  A. I mean, I have relied on company documents. When you say "internal company
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11 12 13 14 15 16 17 18 19 20 21 22	they cite about, to refresh my memory.  Q. As you sit here, you don't remember what those documents are, do you?  A. Yeah. Yeah. I'd have to go back.  Q. Is that correct?  A. Yeah. I mean, I have to go back to my report and see them.  Q. My question is: Did plaintiffs' counsel provide you with a large set of J&J and Imerys company documents and you went through and whittled them down, or did they provide you with select documents?	12 13 14 15 16 17 18 19 20 21 22	job, outside of your litigation consulting work, do you rely on internal company documents?  MS. PARFITT: Objection. Form.  A. I mean, I have relied on company documents. When you say "internal company documents," that's, you know yeah. I have relied on company documents. We have relied on company trial registries for publications. We have relied on whether you're talking about company communication, that's different.  But in terms of if we have data available

	Page 74		Page 76
1	communications, the types of documents that you	1	testimony.
2	cite from or produced by J&J and by Imerys in	2	A. I've already stated that when I publish
3	your reference list.	3	articles, the approach is to gather all relevant,
4	Those are not the types of materials that	4	available evidence.
5	you typically would rely on if you were doing a	5	And I have, in fact you can go back at my
6	study for publication; correct?	6	articles and included data from company
7	MS. PARFITT: Objection. Form.	7	documents in various systematic reviews and
8	A. And, again, I've just said that, you	8	meta-analyses. So this idea that I have not
9	know, I gathered all the relevant evidence, as	9	relied on company documents is you know, is
10	would you know, as a methodology that's	10	not.
11	acceptable and considered.	11	The question is about deposition transcripts
12	But, you know, in my previous reviews, I've	12	and communiques. Those are generally not
13	not had access to access to those documents.	13	available in the published domain, and even for
14	And that's the only that's the only place	14	this particular instance, you know, for there's a
15	where you can get access to these documents.	15	confidentiality order. I'm just trying to
16	Q. The answer to my question is no, you	16	explain what happens.
17	know, when you publish articles, you do not rely	17	Q. So that our record is clear, when you
18	on internal company documents or communications	18	talk about internal communiques, we're talking
19	as you are in this litigation matter; correct?	19	about internal communications, in this case,
20	MS. PARFITT: Objection. Form.	20	materials that you have been provided by
21	A. The reason is because there's a	21	plaintiffs that have been produced by J&J and by
22	confidentiality order. And so you can't say you	22	Imerys.
23	can't publish articles when you can't access	23	Those are not the types of documents that
24	them. I mean, there's a chicken and egg, here,	24	you typically have available and rely upon in
25	right?	25	your published work; correct?
	Page 75		Page 77
1	Q. Understood.	1	MS. PARFITT: Objection. Misstates his
2	The answer, though, to my question is yes;	2	testimony.
3	correct?	3	Q. Is that correct, Doctor?
4	MS. PARFITT: Objection. Form.	4	MS. PARFITT: Objection. Misstates his
5	A. The reason is because these	5	testimony.
6		)	testimony.
	documents	6	<del>-</del>
7	O. Doctor, you need to answer the		A. These are just not available to form an
7 8	Q. Doctor, you need to answer the	6	A. These are just not available to form an opinion in the published domain.
	Q. Doctor, you need to answer the question.	6 7	A. These are just not available to form an
8 9	<ul><li>Q. Doctor, you need to answer the question.</li><li>MS. PARFITT: Wait, Mr. Zellers.</li></ul>	6 7 8	A. These are just not available to form an opinion in the published domain.     Q. You have an additional     THE WITNESS: Can I take a break?
8	Q. Doctor, you need to answer the question.  MS. PARFITT: Wait, Mr. Zellers.  Excuse me. Let the witness answer the question.	6 7 8 9	A. These are just not available to form an opinion in the published domain.  Q. You have an additional THE WITNESS: Can I take a break? MR. ZELLERS: Sure. Of course. At any
8 9 10	Q. Doctor, you need to answer the question.  MS. PARFITT: Wait, Mr. Zellers.  Excuse me. Let the witness answer the question.  MR. ZELLERS: I'm asking him to answer	6 7 8 9 10	A. These are just not available to form an opinion in the published domain.  Q. You have an additional THE WITNESS: Can I take a break? MR. ZELLERS: Sure. Of course. At any time.
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8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Doctor, you need to answer the question.  MS. PARFITT: Wait, Mr. Zellers.  Excuse me. Let the witness answer the question.  MR. ZELLERS: I'm asking him to answer the question and then I'll be happy to move on.  MS. PARFITT: No. You're telling him, say yes. He's trying to answer your question.  Ask him again. He'll answer the question. He's done it twice.  Q. Do you need me to repeat the question?  A. Yes, please.  MR. ZELLERS: Could you read the question?  I'll ask it again.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. These are just not available to form an opinion in the published domain.  Q. You have an additional THE WITNESS: Can I take a break? MR. ZELLERS: Sure. Of course. At any time. THE WITNESS: Sorry about that. MR. ZELLERS: No. That's fine. THE VIDEOGRAPHER: Off the record.  10:22 a.m. (A recess was taken.) THE VIDEOGRAPHER: Here begins media No. 2 in today's deposition of Sonal Singh, M.D., M.P.H. Back on the record, 10:35 a.m. BY MR. ZELLERS: Q. Dr. Singh, are you ready to continue?
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8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Doctor, you need to answer the question.  MS. PARFITT: Wait, Mr. Zellers.  Excuse me. Let the witness answer the question.  MR. ZELLERS: I'm asking him to answer the question and then I'll be happy to move on.  MS. PARFITT: No. You're telling him, say yes. He's trying to answer your question.  Ask him again. He'll answer the question. He's done it twice.  Q. Do you need me to repeat the question?  A. Yes, please.  MR. ZELLERS: Could you read the question?  I'll ask it again.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. These are just not available to form an opinion in the published domain.  Q. You have an additional THE WITNESS: Can I take a break? MR. ZELLERS: Sure. Of course. At any time. THE WITNESS: Sorry about that. MR. ZELLERS: No. That's fine. THE VIDEOGRAPHER: Off the record.  10:22 a.m. (A recess was taken.) THE VIDEOGRAPHER: Here begins media No. 2 in today's deposition of Sonal Singh, M.D., M.P.H. Back on the record, 10:35 a.m. BY MR. ZELLERS: Q. Dr. Singh, are you ready to continue?

	Page 78		Page 80
1	Do you have that?	1	answer the causal question in this case; is that
2	A. Yes.	2	right?
3	Q. There are some documents on this list	3	A. Yes.
4	that have a preface of Imerys. And if you look	4	MS. PARFITT: Objection.
5	on Page 87, you list those documents out. And	5	Q. You did not have access to internal
6	then turning to Page 88, there's a series of	6	documents of J&J companies or of Imerys; is that
7	documents that begin with J&J.	7	right?
8	Do you see those?	8	A. Yes.
9	A. Yes.	9	Q. You asked for those documents, the ones
10	Q. Did you rely on those documents in	10	that would be relevant to you in forming an
11	informing your opinions?	11	answer to the question you were asked of
12	A. No. I mean, I reviewed I don't know	12	plaintiffs' counsel; correct?
13	if I reviewed them in full. I just you know,	13	A. Yeah. Relevant to consider or support
14	they were provided to me.	14	or refute. Yeah.
15	Q. That is, the set of documents that were	15	Q. The documents that were provided to you
16	provided to you by counsel for plaintiffs; is	16	are the documents that appear with a J&J
17	that right?	17	preface preface and an Imerys preface in the
18	A. Yes.	18	reference list, Exhibit 4, and in the additional
19	Q. Are you able, as we sit here, to tell	19	materials and data considered list, Exhibit 5;
20	me what those documents are?	20	correct?
21	A. Yeah. I mean, for example, some of	21	A. Yes.
22	them is, you know, duplicative of expert reports	22	Q. Once you got those documents and you
23	that are listed here. I don't know by number and	23	looked at those documents and you're not sure
24	number, J&J, what that means.	24	you looked at all of them; is that right?
25	Q. I'm referring to, for this series of	25	A. Yes. I did not. I mean
	Page 79		Page 81
1	questions, just to the other materials that you	1	Q. All right.
2	have listed, the ones that begin with Imerys. So	2	A because it is not possible to look
3	starting at Item 2 on Page 87. And then also	3	at all of them.
4	including the documents that begin J&J that go	4	Q. Did you make any follow-up request for
5	through Item 23 on Page 88.	5	additional company documents, either documents
6	Are you able to identify and tell us what	6	produced by J&J or documents produced by Imerys,
7	those documents are?	7	of plaintiffs' counsel?
8	A. I mean, I was provided them. I don't	8	A. I was inundated with these, and I don't
9	know what specifically they are, you know.	9	think it was practical of me to request for
10	Q. Do you know how they were compiled?	10	additional documents.
10			additional devanients.
11	A. No. I'm not aware of the process.	11	Q. In terms of internal company documents
			Q. In terms of internal company documents and communications produced either by
11	<ul><li>A. No. I'm not aware of the process.</li><li>Q. Do you know what percentage of internal documents, internal to Johnson &amp; Johnson</li></ul>	11 12 13	Q. In terms of internal company documents and communications produced either by Johnson & Johnson and by Imerys, the only
11 12 13 14	A. No. I'm not aware of the process.  Q. Do you know what percentage of internal documents, internal to Johnson & Johnson companies and to Imerys, have been produced in	11 12 13 14	Q. In terms of internal company documents and communications produced either by Johnson & Johnson and by Imerys, the only documents you reviewed are the ones that were
11 12 13 14 15	A. No. I'm not aware of the process.  Q. Do you know what percentage of internal documents, internal to Johnson & Johnson companies and to Imerys, have been produced in the case that appear on your reliance list?	11 12 13 14 15	Q. In terms of internal company documents and communications produced either by Johnson & Johnson and by Imerys, the only documents you reviewed are the ones that were hand selected by lawyers for plaintiffs; is that
11 12 13 14 15	A. No. I'm not aware of the process. Q. Do you know what percentage of internal documents, internal to Johnson & Johnson companies and to Imerys, have been produced in the case that appear on your reliance list? A. I'm not aware of that proportion.	11 12 13 14 15 16	Q. In terms of internal company documents and communications produced either by Johnson & Johnson and by Imerys, the only documents you reviewed are the ones that were hand selected by lawyers for plaintiffs; is that right?
11 12 13 14 15 16	<ul> <li>A. No. I'm not aware of the process.</li> <li>Q. Do you know what percentage of internal documents, internal to Johnson &amp; Johnson companies and to Imerys, have been produced in the case that appear on your reliance list?</li> <li>A. I'm not aware of that proportion.</li> <li>Q. Did you request any additional J&amp;J or</li> </ul>	11 12 13 14 15 16 17	Q. In terms of internal company documents and communications produced either by Johnson & Johnson and by Imerys, the only documents you reviewed are the ones that were hand selected by lawyers for plaintiffs; is that right?  MS. PARFITT: Objection. Form.
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	Page 82		Page 84
1	So how can I answer that they were hand	1	Q. It's fair to say you did not rely on
2	selected?	2	the updated materials list in forming your
3	Q. The company documents that you	3	opinions and preparing your report in this case;
4	reviewed, internal company documents, they came	4	correct?
5	from plaintiffs; is that correct?	5	A. Yeah. I did not rely on this, on these
6	A. Yes.	6	materials in preparing the report, but several of
7	Q. The updated materials list, we marked	7	these materials are, you know, are helpful in
8	that as Exhibit 6.	8	explaining my opinions on this, which were, you
9	Those are materials that were provided to	9	know, provided in the report.
10	you by plaintiffs' counsel; is that right?	10	Q. Have you published anywhere your theory
11	A. No. I submitted I mean, I had	11	that baby powder causes ovarian cancer?
12	access to several of these documents, you know,	12	A. I don't consider it my theory. I mean,
13	after the submission of my report, and I reviewed	13	several other people have studied this. I don't
14	them and I actually sent them some of them.	14	know how many studies. There have been more than
15	So	15	30 studies.
16	Q. What documents on this list did you	16	So I don't consider it my theory. But, no,
17	provide to plaintiffs and what documents on this	17	I have not published a study on it.
18	list we're looking at Exhibit 6 did they	18	Q. Do you plan to publish on this?
19	provide to you?	19	A. Yes, I do.
20	A. Like I had the Fadak article. I had	20	Q. Are those plans underway?
21	the Health Canada Assessment. They provided the	21	A. Well, I mean, a lot of it will, again,
22	submitted reports. I had the Weed article. They	22	depend on, you know, the questions you asked
23	provided the Zervo I don't know how to	23	about how much of this material will become
24	pronounce that name. Yeah.	24	eventually you know, I have signed a
25	So, yeah, I had access to some of these, and	25	confidentiality order. So, you know, how much is
	Page 83		Page 85
1	Page 83	1	Page 85
1	I provided the up-to-date article, and the	1	allowed to be published.
2	I provided the up-to-date article, and the remainder, they provided.	2	allowed to be published.  And so, you know, a lot of it will depend
2	I provided the up-to-date article, and the remainder, they provided.  MR. KLATT: May I interject? I didn't	2 3	allowed to be published.  And so, you know, a lot of it will depend on, I guess, the permission of the judge, who
2 3 4	I provided the up-to-date article, and the remainder, they provided.  MR. KLATT: May I interject? I didn't understand the very first article you said. It	2 3 4	allowed to be published.  And so, you know, a lot of it will depend on, I guess, the permission of the judge, who allows who oversees these kind of I would
2 3 4 5	I provided the up-to-date article, and the remainder, they provided.  MR. KLATT: May I interject? I didn't understand the very first article you said. It sounded like dark.	2 3 4 5	allowed to be published.  And so, you know, a lot of it will depend on, I guess, the permission of the judge, who allows who oversees these kind of I would like to, eventually.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I provided the up-to-date article, and the remainder, they provided.  MR. KLATT: May I interject? I didn't understand the very first article you said. It sounded like dark.  THE WITNESS: Fadak.  MS. PARFITT: F-A-D-A-K.  THE WITNESS: Fadak, that's a paper MR. KLATT: Okay. I see. Thank you.  THE WITNESS: That's a 2015 paper.  MR. KLATT: I saw it. Thank you.  BY MR. ZELLERS:  Q. When did you review the materials that are listed on the updated materials list, Exhibit 6?  A. So, again, maybe we circle back earlier when I said I did not review all of them, like I did not review the expert reports. Yeah.  Q. Of the materials that you did review, on the updated materials list, when did you review those?  A. Sometime between December and January.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	allowed to be published.  And so, you know, a lot of it will depend on, I guess, the permission of the judge, who allows who oversees these kind of I would like to, eventually.  Q. Have you previously published on any topic relating to talc and ovarian cancer?  A. No.  Q. Have you conducted any test or experiments to confirm your theory that talc migrates to the ovaries and causes cancer via inflammation?  A. So, again, that is not a theory that I have propounded, that talc migrates through the ovary, that talc migrates up to cause ovarian cancer, that I have evaluated the epidemiologic studies, which show a causal link between talc and ovarian cancer, and several other investigators, some of them which I cite, have provided evidence that of talc-induced, you know, migration.  So it's not my theory, as you say.

22 (Pages 82 to 85)

	Page 86		Page 88
1	question.	1	A. Yeah. It was available to everyone in
2	Have you, Dr. Singh, conducted any test or	2	December.
3	experiments to confirm your statement in your	3	Q. Have you looked into what other public
4	report that talc migrates to the ovaries and	4	health authorities have to say about talc and
5	causes cancer via inflammation?	5	ovarian cancer?
6	A. No. I have not done any experiments.	6	A. Yes.
7	Q. Can you identify for me a single	7	Q. Would it be important for you to know
8	article that identifies inflammation anywhere in	8	that CDC does not list talc as a risk factor for
9	a woman's reproductive tract resulting from	9	ovarian cancer?
10	external genital talc application?	10	MS. PARFITT: Objection. Form.
11	MS. PARFITT: Objection. Form.	11	A. I mean, it would be important to know,
12	A. Can you repeat the question?	12	you know, various agencies, you know, CDC,
13	Q. Sure. Can you identify for me a single	13	whatever. I mean, you would like to know of
14	article that identifies inflammation anywhere in	14	many, many agencies.
15	a woman's reproductive tract resulting from	15	But, again, you'd have to you'd have to
16	external genital talc application?	16	see the quality of their judgment. I mean, what
17	A. I mean, again, this is, you know, when	17	is their rationale? What are the studies they
18	I reviewed so this relates to the biological	18	reviewed? What is the data available?
19	question about talc. And when I reviewed the	19	Just like as you said, what is the data
20	biological evidence, I was on migration and	20	available to me to make that judgment, what is
21	inflammation, I was looking for evidence, support	21	data available to them? Just because they are
22	or refute that.	22	the CDC doesn't mean that, you know yes, I
23	And there's studies that show that talc	23	would like to know their opinion, but then what
24	migrates through HS, you know, whatever,	24	is the underlying basis of their opinion?
25	hysterosalpingography, and induces inflammation.	25	Q. You're familiar with the CDC; correct?
	Page 87		Page 89
1	I mean, the definitive study is not there.	1	A. I'm very familiar with the CDC.
2	And, again, I did not do these studies. So	2	Q. It is an unbiased governmental entity;
3	I can only rely on people who have done such	3	correct?
4	studies.	4	A. Well, it would depend on the opinion.
5	Q. Can you cite a single study, animal or	5	I mean, you know, we cannot say an entity is
6	human, that traces externally applied talc up	6	unbiased. It would depend what is the particular
7	through the reproductive tract to the ovaries?	7	opinion you know, if the CDC provides
8	MS. PARFITT: Objection. Form.	8	vaccination. We have to look at the particular
9	A. Again, but I do not believe that's	9	context.
10	necessary to, you know, provide my causal opinion	10	Q. Are you aware that the CDC does not
11	in support of a causal hypothesis.	11	list tale as a risk factor for ovarian cancer?
12	MR. KLATT: Objection. Nonresponsive.	12	A. Yes.
13	Q. Is the answer to my question, no?	13	MS. PARFITT: Objection.
14	MS. PARFITT: Objection. Form.	14	Q. Are you aware that the Mayo Clinic does
15	A. No, with context.	15	not list tale as a risk factor for ovarian
16	Q. Health Canada Risk Assessment, that was	16	cancer?
17	not something that you included in your	17	A. I'm not aware of Mayo Clinic.
18	references or materials considered as part of	18	Q. You are aware of NIH; correct?
	your report; is that right?	19	A. Yes. I'm funded by the NIH.
19		20	Q. Do you know that NIH does not list talc
19 20	A. Yes. It was not available at that		
	A. Yes. It was not available at that time.	21	as a risk factor for ovarian cancer?
20			as a risk factor for ovarian cancer?  A. Yes. And I have been aware of, you
20 21	time.	21	
20 21 22	time. Q. All right. It is listed, the Health	21 22	A. Yes. And I have been aware of, you

	Page 90		Page 92
1	Fallopian Tube, and Primary Peritoneal	1	not a risk factor for ovarian cancer?
2	Cancer Prevention (PDQ) - Health	2	MS. PARFITT: Objection.
3	Professional Version marked Exhibit 15.)	3	A. So the National Cancer Institute hasn't
4	MR. ZELLERS: Take a look at Deposition	4	opined on that talc is not a causal you know,
5	Exhibit 15.	5	is causally linked to ovarian cancer. It has
6	MS. PARFITT: Thank you.	6	provided a listing of documents. It has not gone
7	BY MR. ZELLERS:	7	through any systematic process, that I'm aware
8	Q. Deposition Exhibit 15 is a publication	8	of, of looking at the epidemiologic data
9	from the National Cancer Institute; is that	9	systematically.
10	right?	10	It has not provided any evidence of
11	A. It is.	11	inflammation or lack thereof or migration or lack
12	Q. National Cancer Institute is a leading	12	thereof or to even, you know, arrive at this
13	health authority; is that right?	13	causal hypothesis.
14	A. Yes.	14	Q. Because it's important to look at both
15	Q. It's a leading cancer research	15	sides of an issue; correct?
16	institution in the world?	16	A. Yes. I did look so I'm saying that
17	MS. PARFITT: Objection. Form.	17	I did look at this and my opinion
18	A. Yes.	18	Q. Did you
19	Q. Have you ever received a grant from the	19	MS. PARFITT: Please let him finish.
20	National Cancer Institute?	20	Q. Are you finished?
21	A. I've applied. I have not received any.	21	A. I'm saying I did look at this, and I'm
22	I am applying again.	22	aware of this document.
23	Q. They fund more cancer research than any	23	Q. Did you cite to the CDC in your report
24	organization in the world; correct?	24	or references?
25	MS. PARFITT: Objection.	25	A. I don't I wasn't aware of the CDC.
	Page 91		Page 93
1	A. I don't know that particular number,	1	Q. Did you cite to the NIH in your report
2	but I just don't know that answer.	2	or your references?
3	Q. Are you aware that the National Cancer	3	A. I should have. And if it isn't, it is
4	Institute reviews the peer-reviewed literature as	4	remiss.
5	it relates to risk factors for ovarian cancer?	5	Q. Did you cite to the National Cancer
6	MS. PARFITT: Objection. Form.	6	Institute in your report or references?
7	A. Yes. And I don't know how updated they	7	A. I have to look at it.
8	are. Based on the document you've provided me,	8	Q. The National Cancer Institute, in fact,
9	they have four citations for perineal talc and	9	has done an analysis, a very detailed analysis
10	ovarian cancer.	10	which we have marked as Exhibit 15 to this
11	So, again, I'm not questioning the NCI's	11	deposition; correct?
11 12	So, again, I'm not questioning the NCI's motivation, but I am I am raising, what is the	11 12	
		12 13	deposition; correct?
12	motivation, but I am I am raising, what is the	12 13 14	deposition; correct?  MS. PARFITT: Objection to form.
12 13	motivation, but I am I am raising, what is the quality of their judgment.	12 13 14 15	deposition; correct?  MS. PARFITT: Objection to form.  A. I don't think it's a detailed analysis
12 13 14	motivation, but I am I am raising, what is the quality of their judgment.  Q. Did you consider the CDC's	12 13 14	deposition; correct?  MS. PARFITT: Objection to form.  A. I don't think it's a detailed analysis of perineal talc and ovarian cancer.  There is how many lines? We can look at it and read it together. It's, you know it's 15
12 13 14 15	motivation, but I am I am raising, what is the quality of their judgment.  Q. Did you consider the CDC's determination that talc is not a risk factor for ovarian cancer in formulating your opinions?  A. Yes.	12 13 14 15	deposition; correct?  MS. PARFITT: Objection to form.  A. I don't think it's a detailed analysis of perineal talc and ovarian cancer.  There is how many lines? We can look at it
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12 13 14 15 16 17	motivation, but I am I am raising, what is the quality of their judgment.  Q. Did you consider the CDC's determination that talc is not a risk factor for ovarian cancer in formulating your opinions?  A. Yes.  Q. Did you consider NIH's determination that talc is not a risk factor for ovarian cancer	12 13 14 15 16 17 18 19	deposition; correct?  MS. PARFITT: Objection to form.  A. I don't think it's a detailed analysis of perineal talc and ovarian cancer.  There is how many lines? We can look at it and read it together. It's, you know it's 15 lines. And they have references 41 to 45, which is five references.  So I don't know it is a detailed analysis.
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24 (Pages 90 to 93)

Page 94  1 Q. All right. This document, this 2 document that we're looking at from the National 3 Cancer Institute, Exhibit 15, was updated in 4 January of 2019 is that right? 5 A. Yeah. But it doesn't mean the review 6 was updated, because it has no recent citations of studies that have been conducted. 8 Q. We - A. We should look at the citation. Let's 10 look at it, because we are discussing this 11 document, so we should look at it in detail. 12 Q. Doctor, turn to Page 6. 13 A. No. Let me finish. I'm not finished 14 with this document. 15 MS. PARFITT: Go ahead. Let him 16 finish. 16 Q. Doctor, you have to answer my 17 questions. 18 A. But I haven't answered it. 19 Q. My question is look at Page 6. Can you 19 do that? 20 A. Okay. 21 A. Okay. 22 A. Okay. 23 Q. All right. Page 6 is a section on 24 perineal tale exposure; is that right? 25 A. Yes. 26 Q. On Page 6, the first sentence under 26 perineal tale exposure and an increased risk of 27 evidence does not support an association between 28 perineal tale exposure and an increased risk of 29 ovarian cancer. 20 ovarian cancer. 21 Is that right? 22 A. Based on what? Based on these 41 to 45 23 citations? Which are an incomplete listing of 24 studies and an incomplete review of the evidence. 25 So I'm just stating that, yes, what is the 26 underlying basis? 40 Q. Doctor - 41 MS. PARFITT: Wait. Let him finish. 41 He's in the middle of a sentence. 42 MS. PARFITT: Wait. Let him finish. 43 A. I. Idon't know if it's the conclusions. 44 but, ves, you read that part of the statement correctly. 45 Q. Why would you rely on Health Canada, 46 but not these other public health organizations? 46 MS. PARFITT: Objection. Misstates his 45 to the state other public health organizations? 46 MS. PARFITT objection. Misstates his 46 the breadth of review of bloogical plausibility, the breadth of review of bloogical plausibility, the breadth of review of bloogical plausibility, the breadth of review of the vidence. 50 Gr Doctor, we then dealth of review of the vidence. 50 Gr Doctor and
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Cancer Institute, Exhibit 15, was updated in January of 2019; is that right?  A. Yeah. But it doesn't mean the review was updated, because it has no recent citations of studies that have been conducted.  B. Q. We A. We should look at the citation. Let's look at it, because we are discussing this document, so we should look at it in detail. Q. Doctor, turn to Page 6. MS. PARFITT: Go ahead. Let him finish.  MS. PARFITT: Go ahead. Let him finish.  MS. PARFITT: Go ahead. Let him finish.  Q. Doctor, you have to answer my questions.  A. But I haven't answered it. Q. Doctor, you have to answer my dot that?  A. Okay. Q. All right. Page 6 is a section on perineal tale exposure; is that right?  A. Yes.  Page 95  Q. This is part of the National Cancer Institute's publication on ovarian, fallopian tube and primary peritoneal cancer prevention; is that right?  A. Page 97  Page 97  Page 97  A. Bused on what? Based on these 41 to 45 Citations? Which are an incomplete listing of studies and an incomplete review of the evidence. So I'm just stating that, yes, what is the underlying basis?  Q. Doctor -  MS. PARFITT: Wait. Let him finish.  A. Beas on what? Based on these 41 to 45 Canada when my report was conducted. So you see -1 relied on the quality of the review and the breadth of review of biological plausibility, the breadth of review of piological plausibility, the breadth of review of, you know, animal studies, applying the Bradford Hill framework, and then forming an opinion. Q. How are you done? A. No. I'm not done. And the Health Canada Assessment came after that. And it so happened their methodology methodology are methodology and opinions are consistent with mine.  So firs not that Thr relying on that. I'm just saying that they are consistent and they came to the same conclusions. Q. What materials and analysis was done by  Page 97  A. George Time.  A. Yes.  Page 97  A. Yes.  Page 97  A. George Time. A. I don't have that. A. I don't have that. A. But of the varian cancer? A. Recrences 41 to 45. Q. How do you
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10   look at it, because we are discussing this document, so we should look at it netatil.   11   12   20   Doctor, turn to Page 6.   12   13   A. No. Let me finish. I'm not finished with this document.   14   31   32   32   33   33   34   35   36   36   37   37   38   39   39   39   39   39   39   39
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12   Q. Doctor, turn to Page 6.   12   Studies, the breadth of review of biological plausibility, the breadth of review of you know, animal studies, applying the Bradford Hill framework, and then forming an opinion.   16   G. How are you done?   17   Q. Doctor, you have to answer my   17   A. No. I'm not done.   18   And the Health Canada Assessment came after that. And it so happened their methodology
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17 Cancer Institute?  18 MS. PARFITT: Wait. Let him finish. 19 He's in the middle of a sentence. 20 A. What is the underlying basis of this 17 Cancer Institute? 28 Q. I'm asking you: Do you know what specific studies and materials were reviewed and what analysis was done by NIH and by the National
18 MS. PARFITT: Wait. Let him finish. 19 He's in the middle of a sentence. 19 A. What is the underlying basis of this 20 A. What is the underlying basis of this
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A. What is the underlying basis of this 20 what analysis was done by NIH and by the National
21 opinion? 21 Cancer Institute?
Q. Dr. Singh, my question is: Did I read 22 A. Yeah. These are the studies that were
23 the conclusion of the National Cancer Institute 23 reviewed.
24 correctly?   24 () You are assuming that this is the
24 correctly? 24 Q. You are assuming that this is the 25 MS. PARFITT: Objection. 25 entire analysis and review that was done by the

	Page 98		Page 100
1	National Cancer Institute; is that right?	1	assessment prior to its publication?
2	MS. PARFITT: Objection. Form.	2	A. No.
3	A. I'm not assuming anything. I'm	3	Q. Have you submitted any comments to
4	assuming that, just as the conclusions that you	4	Health Canada?
5	are assuming are definitive, I'm also, you know,	5	A. No.
6	stating that these are the studies that they	6	Q. Do you intend to submit any comments to
7	relied on to form those conclusions.	7	Health Canada?
8	So we can't pick and choose, assess	8	A. I don't know. I mean, it will depend
9	statement of the excerpt that you supports	9	on the timeline and I don't know what their
10	your opinion, but then not look at the underlying	10	timeline is and what my you know, I
11	evidence base that supports that opinion.	11	haven't I haven't thought about it.
12	Q. But we should consider all of that	12	Q. Outside of your litigation consulting,
13	information; correct?	13	do you generally rely on draft assessments by
14	A. Yeah. And the studies underlying.	14	regulatory agencies?
15	Q. And you did not consider the CDC's	15	MS. PARFITT: Objection. Form.
16	opinion in your report, did you?	16	A. Yes. I mean, you know, we look at
17	A. I mean, CDC so let's just step back	17	draft assessments on regulatory. There's no
18	a little.	18	reason not to.
19	When I say CDC opinion, I mean, I'm looking	19	Q. Have you ever cited a draft assessment
20	at original studies. I'm looking at data in	20	by a regulatory agency in any study that you've
21	forming my opinion. I did look at what IARC	21	published?
22	considered and other agencies considered.	22	A. Oh, I've published 200 papers, and I
23	My opinion is based on my review and the	23	can't recall, you know, which one, but I know
24	methodology and I was, you know, obviously,	24	that I have looked at draft assessments by the
25	taking into account what agencies say, but	25	FDA.
	Page 99		Page 101
1	agencies' opinion is not necessarily the	1	Q. Have you cited any?
2	underlying basis of my causal opinion.	2	A. I can't recall and tell you that. It's
3	Q. Whether it's CDC, NIH, NCI or Health	3	just something I can't recall.
4	Canada; correct?	4	Q. Are you familiar with the precautionary
5	A. Yeah. I mean, they're informing. I	5	principle?
6	want to look at their thinking and what is the	6	A. Yes.
7	quality of their judgment on this.	7	Q. What is the precautionary principle?
8	Q. You understand Health Canada has simply	8	A. It is to, you know, apply, as my
9	produced a draft assessment; is that right?	9	understanding, is to warn when there is, you
10	MS. PARFITT: Objection. Form.	10	know, evidence of a hazard.
11	A. Yes.	11	Q. That's your understanding of the
12	Q. We are at the beginning of the public	12	precautionary principle?
13	comment period; is that right?	13	A. Yeah.
14	A. I don't know the timeline of that.	14	Q. Do you understand that, as defined by
			TT 14 G 1
15	Q. Are you aware that Health Canada can	15	Health Canada, a precautionary principle means
15 16	take up to two years to take any action or no	16	taking a precautionary approach to
15 16 17	take up to two years to take any action or no action at all?	16 17	taking a precautionary approach to decision-making that emphasizes the need to take
15 16 17 18	take up to two years to take any action or no action at all?  A. Well, I mean, I was not asked a causal	16 17 18	taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of
15 16 17 18 19	take up to two years to take any action or no action at all?  A. Well, I mean, I was not asked a causal question on what to do about this. I was just	16 17 18 19	taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of a full scientific demonstration of cause and
15 16 17 18 19 20	take up to two years to take any action or no action at all?  A. Well, I mean, I was not asked a causal question on what to do about this. I was just asked a question on causality. And I'm not sort	16 17 18 19 20	taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of a full scientific demonstration of cause and effect?
15 16 17 18 19 20 21	take up to two years to take any action or no action at all?  A. Well, I mean, I was not asked a causal question on what to do about this. I was just asked a question on causality. And I'm not sort of I'm not privy to their process.	16 17 18 19 20 21	taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of a full scientific demonstration of cause and effect?  A. If you're stating well, let's get
15 16 17 18 19 20 21 22	take up to two years to take any action or no action at all?  A. Well, I mean, I was not asked a causal question on what to do about this. I was just asked a question on causality. And I'm not sort of I'm not privy to their process.  Q. How did you come to learn of the Health	16 17 18 19 20 21 22	taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of a full scientific demonstration of cause and effect?  A. If you're stating well, let's get the document out before we
15 16 17 18 19 20 21 22 23	take up to two years to take any action or no action at all?  A. Well, I mean, I was not asked a causal question on what to do about this. I was just asked a question on causality. And I'm not sort of I'm not privy to their process.  Q. How did you come to learn of the Health Canada Risk Assessment?	16 17 18 19 20 21 22 23	taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of a full scientific demonstration of cause and effect?  A. If you're stating well, let's get the document out before we  Q. Sure. Take a look at deposition
15 16 17 18 19 20 21 22 23 24	take up to two years to take any action or no action at all?  A. Well, I mean, I was not asked a causal question on what to do about this. I was just asked a question on causality. And I'm not sort of I'm not privy to their process.  Q. How did you come to learn of the Health Canada Risk Assessment?  A. News, news documents.	16 17 18 19 20 21 22 23 24	taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of a full scientific demonstration of cause and effect?  A. If you're stating well, let's get the document out before we  Q. Sure. Take a look at deposition Exhibit 16.
15 16 17 18 19 20 21 22 23	take up to two years to take any action or no action at all?  A. Well, I mean, I was not asked a causal question on what to do about this. I was just asked a question on causality. And I'm not sort of I'm not privy to their process.  Q. How did you come to learn of the Health Canada Risk Assessment?	16 17 18 19 20 21 22 23	taking a precautionary approach to decision-making that emphasizes the need to take timely preventative action even in the absence of a full scientific demonstration of cause and effect?  A. If you're stating well, let's get the document out before we  Q. Sure. Take a look at deposition

26 (Pages 98 to 101)

	Page 102		Page 104
1	Canada Decision-Making Framework for	1	precautionary approach. A key feature of
2	Identifying, Assessing, and Managing Health	2	managing health risk is that decisions are often
3	Risks - August 1, 2000" marked Exhibit 16.)	3	made in the presence of considerable scientific
4	A. Okay. Can you point out which page?	4	uncertainty. A precautionary approach to
5	Q. Sure. Take a look at Pages 8 and 9.	5	decision-making emphasizes the need to take
6	So we identify it for the record, Exhibit 16 is	6	timely and appropriately preventative action,
7	the Health Canada Decision-Making Framework for	7	even in the absence of a full scientific
8	Identifying, Assessing and Managing Health Risk;	8	demonstration of cause and effect."
9	is that right?	9	Did I read that correctly?
10	A. Yes.	10	A. Okay.
11	Q. If you go to Page 8 and 9, Section 1.3	11	Q. Do you agree that the recommendation by
12	are the underlying principles for Health Canada;	12	Health Canada does not require a finding of
13	is that right?	13	causation like is required in a court; correct?
14	MS. PARFITT: Objection.	14	MS. PARFITT: Objection. Form.
15	MR. TISI: You're looking at the wrong	15	A. But I mean, that's what they conclude,
16	document. You're not looking at the draft	16	that there is a cause. We can look at the Health
17	assessment. You're looking at the	17	Canada document.
18	MR. ZELLERS: Counsel, I am	18	Q. Is a guiding principle of the Health
19	MR. TISI: But you identified something	19	Canada Decision-Making and Assessment to use a
20	as something different than what it is.	20	precautionary approach?
21	MR. ZELLERS: I identified the document	21	MS. PARFITT: Objection. Form.
22	as Health Canada Decision-Making Framework for	22	A. Well, no. I mean, precautionary
23	Identifying, Assessing and Managing Health Risk.	23	they are just defining a precautionary approach.
24	I'm reading the title of the document.	24	But when they assess talc for its whatever, you
25	MR. TISI: Okay. I have it wrong. Go	25	know, the talcum powder products, their
23	MK. 1151. Okay. I have it wrong. Go	23	know, the taleum powder products, then
	Page 103		Page 105
1	ahead.	1	particular assessment clearly states it's causal.
2	MR. ZELLERS: That's okay.	2	And we should open that document. We should not
3	A. Wherever we are.	3	talk about it in hypotheticals.
4	Q. No problem, Doctor.	4	Q. On what basis are you relying to state
5	MS. PARFITT: We'll orient ourselves.	5	that Health Canada did not use a precautionary
6	Q. Are we oriented?	6	approach in assessing talcum powder?
7	A. Yeah. I know the document. But the	7	MS. PARFITT: Objection. Form.
Ω			
8	page number.	8	A. No. No. No. Let me answer that
9	page number. Q. Look at Pages 8 and 9.	8 9	A. No. No. Let me answer that question.
_	Q. Look at Pages 8 and 9.		question.
9	<ul><li>Q. Look at Pages 8 and 9.</li><li>A. Okay.</li></ul>	9	question. You were asking about decision-making.
9	<ul><li>Q. Look at Pages 8 and 9.</li><li>A. Okay.</li><li>Q. 1.3 are the underlying principles for</li></ul>	9	question.
9 10 11	<ul><li>Q. Look at Pages 8 and 9.</li><li>A. Okay.</li><li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li></ul>	9 10 11	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that.
9 10 11 12	<ul><li>Q. Look at Pages 8 and 9.</li><li>A. Okay.</li><li>Q. 1.3 are the underlying principles for</li></ul>	9 10 11 12	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about
9 10 11 12 13	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> </ul>	9 10 11 12 13	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document
9 10 11 12 13 14	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying</li> </ul>	9 10 11 12 13 14	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal
9 10 11 12 13 14 15	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> </ul>	9 10 11 12 13 14 15	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship.
9 10 11 12 13 14 15	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> <li>One of those is to use a precautionary</li> </ul>	9 10 11 12 13 14 15 16	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship. Why aren't you bringing that document out?
9 10 11 12 13 14 15 16 17	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> </ul>	9 10 11 12 13 14 15 16 17	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship. Why aren't you bringing that document out? I mean, you can't talk about documents without
9 10 11 12 13 14 15 16 17 18	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> <li>One of those is to use a precautionary approach; is that right?</li> <li>A. Yes.</li> </ul>	9 10 11 12 13 14 15 16 17 18	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship. Why aren't you bringing that document out? I mean, you can't talk about documents without documents.
9 10 11 12 13 14 15 16 17 18 19 20	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> <li>One of those is to use a precautionary approach; is that right?</li> <li>A. Yes.</li> <li>Q. If you then turn to Page 11, at the</li> </ul>	9 10 11 12 13 14 15 16 17 18 19 20	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship. Why aren't you bringing that document out? I mean, you can't talk about documents without documents. Q. Dr. Singh
9 10 11 12 13 14 15 16 17 18 19 20 21	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> <li>One of those is to use a precautionary approach; is that right?</li> <li>A. Yes.</li> <li>Q. If you then turn to Page 11, at the bottom, they define use of a precautionary</li> </ul>	9 10 11 12 13 14 15 16 17 18 19 20 21	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship. Why aren't you bringing that document out? I mean, you can't talk about documents without documents. Q. Dr. Singh A. Yeah.
9 10 11 12 13 14 15 16 17 18 19 20 21 22	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> <li>One of those is to use a precautionary approach; is that right?</li> <li>A. Yes.</li> <li>Q. If you then turn to Page 11, at the bottom, they define use of a precautionary approach; is that right?</li> </ul>	9 10 11 12 13 14 15 16 17 18 19 20 21 22	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship. Why aren't you bringing that document out? I mean, you can't talk about documents without documents. Q. Dr. Singh A. Yeah. Q do you have any basis to state
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> <li>One of those is to use a precautionary approach; is that right?</li> <li>A. Yes.</li> <li>Q. If you then turn to Page 11, at the bottom, they define use of a precautionary approach; is that right?</li> <li>A. Yes.</li> <li>A. Yes.</li> </ul>	9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship. Why aren't you bringing that document out? I mean, you can't talk about documents without documents. Q. Dr. Singh A. Yeah. Q do you have any basis to state that, in evaluating talcum powder, Health Canada
9 10 11 12 13 14 15 16 17 18 19 20 21 22	<ul> <li>Q. Look at Pages 8 and 9.</li> <li>A. Okay.</li> <li>Q. 1.3 are the underlying principles for Health Canada decision-making.</li> <li>Do you see that?</li> <li>A. Yes.</li> <li>Q. They list out a number of underlying principles on Pages 8 and 9.</li> <li>One of those is to use a precautionary approach; is that right?</li> <li>A. Yes.</li> <li>Q. If you then turn to Page 11, at the bottom, they define use of a precautionary approach; is that right?</li> </ul>	9 10 11 12 13 14 15 16 17 18 19 20 21 22	question. You were asking about decision-making. Decision-making would be removal of talc, removal of that. But there's two parts to that question about cause and effect. So let's bring the document out and say where they state there is a causal relationship. Why aren't you bringing that document out? I mean, you can't talk about documents without documents. Q. Dr. Singh A. Yeah. Q do you have any basis to state

27 (Pages 102 to 105)

		<del></del>	
	Page 106		Page 108
1	MS. PARFITT: Objection. Form.	1	A. No.
2	Misstates the evidence.	2	Q. Hold on. Stop. Stop.
3	A. Yeah. But that does not preclude at	3	A. Sure.
4	arriving at a causal opinion. Just because you	4	Q. Just so we're clear, the updated
5	have a precautionary approach, you can still	5	materials list is a list that was created by
6	arrive at causal opinion, which they did.	6	plaintiffs' counsel; correct?
7	So this is this principle is not	7	MS. PARFITT: It was based upon
8	inconsistent with their report on a causal	8	materials that we had either sent or we had sent
9	opinion.	9	that he also had; correct.
10	Q. The standard under a precautionary	10	MR. ZELLERS: This Exhibit 6 is a list
11	approach is that decisions can be made even in	11	of materials that were provided by plaintiffs'
12	the absence of a full scientific demonstration of	12	counsel to Dr. Singh, understanding that
13	cause and effect; correct?	13	Dr. Singh has testified that he independently had
14	MS. PARFITT: Objection. Form.	14	access to some of the materials.
15	A. That is a threshold, but that does not	15	MS. PARFITT: Correct. Including
16	preclude the determination of cause and effect,	16	Taher.
17	which has been done already.	17	THE WITNESS: Yeah. And some of them,
18	Q. Are you familiar with the Taher 2018	18	I added, such as some of the published articles
19	publication?	19	and Health Canada.
20	A. Taher. I don't know which one.	20	BY MR. ZELLERS:
21	Q. T-A-H-E-R.	21	Q. You have read the Taher 2018
22	A. Yes.	22	manuscript; is that right?
23	Q. Are you familiar with that publication?	23	A. I mean, I read the yeah, I mean,
24	A. Yeah. It was cited in the Health	24	primarily, I read their assessment in Health
25	Canada document.	25	Canada.
	Page 107		
	rage ro,		Page 109
1		1	Page 109  MR. ZELLERS: Deposition Exhibit
1 2	Q. Have you reviewed and analyzed that publication?	1 2	
	Q. Have you reviewed and analyzed that		MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you
2	Q. Have you reviewed and analyzed that publication?	2	MR. ZELLERS: Deposition Exhibit well, strike that.
2	<ul><li>Q. Have you reviewed and analyzed that publication?</li><li>A. I mean, I reviewed it. I don't know if</li></ul>	2 3	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you
2 3 4	<ul> <li>Q. Have you reviewed and analyzed that publication?</li> <li>A. I mean, I reviewed it. I don't know if I analyzed it.</li> <li>What do you mean by "analyzed"?</li> <li>Q. You have not included it on your</li> </ul>	2 3 4	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at
2 3 4 5	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?	2 3 4 5	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes.
2 3 4 5 6	<ul> <li>Q. Have you reviewed and analyzed that publication?</li> <li>A. I mean, I reviewed it. I don't know if I analyzed it.</li> <li>What do you mean by "analyzed"?</li> <li>Q. You have not included it on your</li> </ul>	2 3 4 5 6	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right?
2 3 4 5 6 7	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or	2 3 4 5 6 7	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes.
2 3 4 5 6 7 8	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or updated materials; is that right?	2 3 4 5 6 7 8	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes. Q. One of the underlying documents and
2 3 4 5 6 7 8 9	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or updated materials; is that right?  MS. PARFITT: Objection.  A. It was part of the Health Canada. It should have been part, because it was part, in my	2 3 4 5 6 7 8	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes. Q. One of the underlying documents and studies on which Health Canada reviewed was the Taher article; is that right? A. Yes.
2 3 4 5 6 7 8 9	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or updated materials; is that right?  MS. PARFITT: Objection.  A. It was part of the Health Canada. It	2 3 4 5 6 7 8 9	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes. Q. One of the underlying documents and studies on which Health Canada reviewed was the Taher article; is that right? A. Yes. (Document entitled "Systematic
2 3 4 5 6 7 8 9 10	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or updated materials; is that right?  MS. PARFITT: Objection.  A. It was part of the Health Canada. It should have been part, because it was part, in my mind, part of the Health Canada Assessment.  Q. Can you show me where	2 3 4 5 6 7 8 9 10 11 12	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes. Q. One of the underlying documents and studies on which Health Canada reviewed was the Taher article; is that right? A. Yes. (Document entitled "Systematic Review and Meta-Analysis of the Association
2 3 4 5 6 7 8 9 10 11	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or updated materials; is that right?  MS. PARFITT: Objection.  A. It was part of the Health Canada. It should have been part, because it was part, in my mind, part of the Health Canada Assessment.  Q. Can you show me where  A. Well, I haven't.	2 3 4 5 6 7 8 9 10 11 12 13	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes. Q. One of the underlying documents and studies on which Health Canada reviewed was the Taher article; is that right? A. Yes. (Document entitled "Systematic Review and Meta-Analysis of the Association between Perineal Use of Talc and Risk of
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or updated materials; is that right?  MS. PARFITT: Objection.  A. It was part of the Health Canada. It should have been part, because it was part, in my mind, part of the Health Canada Assessment.  Q. Can you show me where  A. Well, I haven't.  Q the Taher publication is listed in	2 3 4 5 6 7 8 9 10 11 12 13 14 15	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes. Q. One of the underlying documents and studies on which Health Canada reviewed was the Taher article; is that right? A. Yes. (Document entitled "Systematic Review and Meta-Analysis of the Association between Perineal Use of Talc and Risk of Ovarian Cancer" marked Exhibit 17.)
2 3 4 5 6 7 8 9 10 11 12 13	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or updated materials; is that right?  MS. PARFITT: Objection.  A. It was part of the Health Canada. It should have been part, because it was part, in my mind, part of the Health Canada Assessment.  Q. Can you show me where  A. Well, I haven't.  Q the Taher publication is listed in your updated materials which we marked as	2 3 4 5 6 7 8 9 10 11 12 13	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes. Q. One of the underlying documents and studies on which Health Canada reviewed was the Taher article; is that right? A. Yes. (Document entitled "Systematic Review and Meta-Analysis of the Association between Perineal Use of Talc and Risk of Ovarian Cancer" marked Exhibit 17.) BY MR. ZELLERS:
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Have you reviewed and analyzed that publication?  A. I mean, I reviewed it. I don't know if I analyzed it.  What do you mean by "analyzed"?  Q. You have not included it on your references or additional materials considered or updated materials; is that right?  MS. PARFITT: Objection.  A. It was part of the Health Canada. It should have been part, because it was part, in my mind, part of the Health Canada Assessment.  Q. Can you show me where  A. Well, I haven't.  Q the Taher publication is listed in	2 3 4 5 6 7 8 9 10 11 12 13 14 15	MR. ZELLERS: Deposition Exhibit well, strike that. Q. What you told me, when I asked you about CDC and NIH and NCI, is you got to look at the underlying documents, the underlying studies; is that right? A. Yes. Q. One of the underlying documents and studies on which Health Canada reviewed was the Taher article; is that right? A. Yes. (Document entitled "Systematic Review and Meta-Analysis of the Association between Perineal Use of Talc and Risk of Ovarian Cancer" marked Exhibit 17.) BY MR. ZELLERS: Q. The Taher article is what we have
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28 (Pages 106 to 109)

	Page 110		Page 112
1	2018 article?	1	Q. Why did you rely on this article,
2	A. Yeah. I requested access from the	2	Taher, Exhibit 17?
3	attorneys, if they had it. They provided it.	3	MS. PARFITT: Objection to form.
4	Q. So plaintiffs' attorneys provided you	4	A. I mean, when you say I relied on, I
5	with access to the article we've marked as	5	mean, I reviewed the, again, Health Canada
6	Exhibit 17 prior to its publication; is that	6	Assessment. So none of this is in isolation.
7	right?	7	I mean, this is just a part of, you know,
8	A. Yeah.	8	the body of evidence. You know, my testimony
9	MS. PARFITT: Objection.	9	relies on and my report relies on the evidence
10	A. I don't know if it has been published	10	cited there.
11	yet.	11	This is, you know, another meta-analysis
12	Q. Did you have access to the appendices	12	that, you know, I reviewed the evidence in
13	or supplemental tables referenced in the Taher	13	slightly different ways and came to the same
14	publication?	14	conclusions and, you know, also did a causal
15	A. Yes, I did.	15	analysis. So it's sort of, you know, you have to
16	Q. In your epidemiologic strike that.	16	review what evidence comes out.
17	Is the Taher publication, which we've marked	17	If another meta-analysis comes out tomorrow,
18	as Exhibit 17, is that peer-reviewed?	18	then I would review it.
19	A. It's peer-reviewed, and I assume that	19	Q. Do you know the source of funding for
20	it's going to be published. And it was reviewed	20	this publication?
21	by Health Canada. So I mean, it is	21	A. I don't know. I mean, Health Canada or
22	peer-reviewed, is my understanding.	22	something else, I don't know that. I can't
23	It is I don't know the exact status of	23	answer that question.
24	that manuscript.	24	Q. You're assuming that Health Canada is
25	Q. What organization has peer-reviewed the	25	the source of funding for this publication?
	Page 111		Page 113
1	Taher publication, Exhibit 17?	1	A. I don't know. I shouldn't answer that.
2	A. So I don't yeah, again, I take it	2	Q. Do you know the credentials of the
3	I don't know the status of that manuscript, where	3	authors of the Taher 2018 publication,
4	it is.	4	Exhibit 17?
5			
	Q. You do not know, one way or the other,	5	A. I have no idea.
6	Q. You do not know, one way or the other, as to whether the Taher publication. Exhibit 17.	5	A. I have no idea.
6 7	as to whether the Taher publication, Exhibit 17,		<ul><li>A. I have no idea.</li><li>Q. Do you personally know any of the</li></ul>
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	Page 114		Page 116
1	MS. PARFITT: Objection.	1	sentence. And I'll read it. Have you found
2	A. That's a very vague and broad question.	2	Page 41 of Exhibit 17?
3	I mean, conflicts of interest as it relates to	3	A. 41?
4	what?	4	Q. Yes. Page 41. Do you have that?
5	Q. Do you know?	5	A. Yeah. Yeah.
6	MS. PARFITT: Objection. Form.	6	Q. The very last
7	A. As it relates to what?	7	A. Yeah. I'm looking at it.
8	Q. You told me you don't know any of the	8	Q. Tell me if I read this correctly. "The
9	authors; right?	9	similarity of findings between studies published
10	A. Yeah.	10	prior to and after this point suggest asbestos
11	Q. I've now asked you if you know if any	11	contamination does not explain the positive
12	of the authors had conflicts of interest.	12	association between perineal use of talc powder
13	A. And I'm saying that I'm reading the	13	and risk of ovarian cancer."
14	article and I'm reading their declaration, and	14	Did I read that correctly?
15	that's the only way to find out that they have	15	A. Yes.
16	conflicts of interest, right.	16	Q. Do you disagree with the authors on
17	Q. I should be more precise.	17	that point?
18	A. Yeah.	18	A. Let me just read it.
19	Q. Of your own personal knowledge, do you	19	Well, I mean, to the extent that they are
20	know whether or not any of the authors have	20	aware that asbestos does not contaminate talc
21	conflicts of interest?	21	is not contaminated with asbestos, I do agree.
22	A. That's a separate	22	But, again, I have, you know, obviously more
23	MS. PARFITT: Objection.	23	information on that.
24	A. So what I'm trying to say is, you know,	24	Q. On Page 25 of Exhibit 17, the Taher
25	when you ask about conflicts of interest, if you	25	2018 article, is a table entitled "Summary of
	Page 115		Page 117
1	want to ask about my article, you'd have to go	1	Evidence for Each of the Hill Criteria of
2	and read the article and see that, what is stated	2	Causation as Applied to Perineal Application of
3	there.	3	Talc and Ovarian Cancer."
4	So that's what I'm trying to answer when you	4	Is that right?
5	ask. I'm trying to be honest and truthful about	5	A. Yes.
6	my answers.	6	Q. One of the Hill criteria is
7	MR. KLATT: Objection; nonresponsive.	7	consistency; is that right?
8	MR. ZELLERS: Move to strike as	8	MS. PARFITT: Objection. Form.
9	nonresponsive.	9	A. Yes.
10	THE WITNESS: I didn't understand the	10	Q. Looking at authors' statement on
11	question.	11	consistency, it states, "15 out of the 30 studies
12	MR. LOCKE: We all have questions to	12	reported positive and significant associations."
13	ask this witness. We're not going to make the	13	Is that right?
14	seven hours with these answers that do not answer	14	A. Yes.
15	the questions.	15	Q. 15 out of 30, that's 50 percent; is
16	THE WITNESS: Maybe I'm not	16	that right?
17	understanding the question. I'm sorry. It's not	17	MS. PARFITT: Objection. Form.
18	that I'm trying to	18	A. Yeah. But I have I disagree with
	Q. Dr. Singh, the authors of the Taher	19	their interpretation of consistency as being, you
19	paper concluded that the evidence suggests that	20	know, statistically significant. I mean, you
19 20	puper concluded that the cyladrice suggests that	I	know, my assessment is, you know, estimates
	asbestos contamination does not explain the	21	know, my assessment is, you know, estimates
20		21 22	towards greater than one.
20 21	asbestos contamination does not explain the	1	
20 21 22	asbestos contamination does not explain the positive association between perineal use of talc	22	towards greater than one.

30 (Pages 114 to 117)

	Page 118		Page 120
1	50 percent?	1	consistent evidence. There are studies that
2	A. Yes.	2	provide dose-response and other studies that
3	MS. PARFITT: Objection. Let me	3	don't.
4	object, please.	4	Q. You currently work for the University
5	Q. That's no better than a coin toss;	5	of Massachusetts; is that right?
6	correct?	6	A. Yes.
7	MS. PARFITT: Object to the form.	7	Q. You work for both the medical school
8	A. It is 50 percent.	8	and the medical center; is that right?
9	Q. Would you say that 15 out of 30 means	9	A. Yes.
10	there are consistent results across studies?	10	Q. Are you aware that the University of
11	A. Well, I mean, again, my definition of	11	Massachusetts does not claim that talcum powder
12	inconsistency, as noted in my report, is	12	causes ovarian cancer?
13	different from theirs.	13	MS. PARFITT: Objection. Form.
14	Q. These are just the case control	14	A. I don't know what they're listed on
15	studies; is that right?	15	their website. I'm not sure they provide any
16	A. When you say they just say 30	16	information sheet that I am aware of.
17	studies. Yeah.	17	(Printout entitled "Ovarian
18	Q. These are case-control studies; is that	18	Cancer: Risk Factors" marked Exhibit 18.)
19	right?	19	BY MR. ZELLERS:
20	MS. PARFITT: Objection. Form.	20	Q. Take a look, if you will, at Deposition
21	A. Well, they're both, right? Case	21	Exhibit 18.
22	control and core.	22	MR. TISI: What is 16?
23	Q. The authors in Taher also recognize	23	MR. ZELLERS: Exhibit 16 was the Health
24	that there's no consistent dose-response across	24	Canada Decision-Making Framework. It's right
25	studies; is that right?	25	here.
	Page 119		Page 121
1	MS. PARFITT: Objection. Form.	1	MR. TISI: Oh. I have that, Counsel.
2	A. Well, let me look at the dose-response	2	Thank you.
3	section.	3	BY MR. ZELLERS:
4	Q. Page 21. And I'm looking at the very	4	Q. Have you had an opportunity, Dr. Singh,
5	last sentence above Section 3.3.2.	5	to review Deposition Exhibit 18?
6	A. Tell me, which page number?	6	A. Yes.
7	Q. Sure. Page 21.	7	Q. This is a website from the University
8	A. We do have to slow down so that I can	8	of Massachusetts Memorial Healthcare; is that
9	move between pages, if you don't mind.	9	right?
10	Yes.	10	A. Yes.
11	Q. This is in the section "Evidence from	11	Q. Are you familiar with the website?
12	Human Studies"; correct?	12	A. I mean, overall website, but not this
13	A. Okay.	13	particular document.
13 14	<ul><li>A. Okay.</li><li>Q. Is that a yes?</li></ul>	13 14	Q. On the second page of Exhibit 18,
14 15	<ul><li>Q. Is that a yes?</li><li>A. Yes.</li></ul>	14 15	Q. On the second page of Exhibit 18, there's a statement by your employer, the
14 15 16	<ul><li>Q. Is that a yes?</li><li>A. Yes.</li><li>Q. The statement by the authors, "When</li></ul>	14 15 16	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum
14 15 16 17	<ul><li>Q. Is that a yes?</li><li>A. Yes.</li><li>Q. The statement by the authors, "When conducted, findings from trend analyses were not</li></ul>	14 15 16 17	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.
14 15 16 17 18	<ul><li>Q. Is that a yes?</li><li>A. Yes.</li><li>Q. The statement by the authors, "When conducted, findings from trend analyses were not consistent."</li></ul>	14 15 16 17 18	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.  Do you see that?
14 15 16 17	<ul><li>Q. Is that a yes?</li><li>A. Yes.</li><li>Q. The statement by the authors, "When conducted, findings from trend analyses were not</li></ul>	14 15 16 17 18 19	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.  Do you see that?  A. Yes.
14 15 16 17 18	<ul> <li>Q. Is that a yes?</li> <li>A. Yes.</li> <li>Q. The statement by the authors, "When conducted, findings from trend analyses were not consistent."</li> <li>Is that right?</li> <li>A. The last line?</li> </ul>	14 15 16 17 18 19 20	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.  Do you see that?  A. Yes.  Q. The statement is, "It's not clear if
14 15 16 17 18 19 20 21	<ul> <li>Q. Is that a yes?</li> <li>A. Yes.</li> <li>Q. The statement by the authors, "When conducted, findings from trend analyses were not consistent."</li> <li>Is that right?</li> <li>A. The last line?</li> <li>Q. Yes.</li> </ul>	14 15 16 17 18 19 20 21	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.  Do you see that?  A. Yes.  Q. The statement is, "It's not clear if using talcum powder on the genital area raises
14 15 16 17 18 19	<ul> <li>Q. Is that a yes?</li> <li>A. Yes.</li> <li>Q. The statement by the authors, "When conducted, findings from trend analyses were not consistent."</li> <li>Is that right?</li> <li>A. The last line?</li> </ul>	14 15 16 17 18 19 20	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.  Do you see that?  A. Yes.  Q. The statement is, "It's not clear if using talcum powder on the genital area raises the risk for ovarian cancer. Talk with your
14 15 16 17 18 19 20 21	<ul> <li>Q. Is that a yes?</li> <li>A. Yes.</li> <li>Q. The statement by the authors, "When conducted, findings from trend analyses were not consistent."</li> <li>Is that right?</li> <li>A. The last line?</li> <li>Q. Yes.</li> <li>A. Yes. But the criteria for dose-response is just exposure-response</li> </ul>	14 15 16 17 18 19 20 21 22 23	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.  Do you see that?  A. Yes.  Q. The statement is, "It's not clear if using talcum powder on the genital area raises the risk for ovarian cancer. Talk with your healthcare provider if you decide you want to use
14 15 16 17 18 19 20 21	<ul> <li>Q. Is that a yes?</li> <li>A. Yes.</li> <li>Q. The statement by the authors, "When conducted, findings from trend analyses were not consistent."</li> <li>Is that right?</li> <li>A. The last line?</li> <li>Q. Yes.</li> <li>A. Yes. But the criteria for</li> </ul>	14 15 16 17 18 19 20 21 22	Q. On the second page of Exhibit 18, there's a statement by your employer, the University of Massachusetts, on use of talcum powder.  Do you see that?  A. Yes.  Q. The statement is, "It's not clear if using talcum powder on the genital area raises the risk for ovarian cancer. Talk with your

31 (Pages 118 to 121)

	Page 122		Page 124
1	A. Yes, you did.	1	take a look at Exhibit 2 or Exhibit 10, whichever
2	Q. Why doesn't your institution list talc	2	is easier for you.
3	exposure as a risk factor for ovarian cancer?	3	A. Page 66?
4	MS. PARFITT: Objection. Misstates the	4	Q. Yes. Your conclusion.
5	evidence.	5	A. Yes.
6	A. So, yeah, I mean, first of all, this	6	Q. You state that peritoneal use of talcum
7	is I've seen this the first time here, but as	7	powder products can cause ovarian cancer;
8	you can see, again, this is we have to go to	8	correct?
9	Page 3 of 4 and it's medical reviewers and they	9	A. Yes.
10	are, you know, basing their opinion on whatever.	10	Q. Is it your opinion that it does cause
11	This was done in 2013.	11	ovarian cancer or just that it can?
12	So it depends on the it's not that, you	12	MS. PARFITT: Objection to form.
13	know, my medical, you know, employer is listing	13	A. I don't know the semantics of what
14	it. Obviously, it's listed there.	14	would be if semantics of can and does. I
15	And but it's based on the quality of the	15	mean, you can explain to me. Maybe my English is
16	evidence. This was reviewed on 2016, and it was	16	not as good as yours.
17	reviewed by, as you see, the credentials of	17	Q. What type of exposure causes ovarian
18	did they review the did they review the	18	cancer?
19	biological evidence? Did they have any	19	A. Perineal application. So I mean, are
20	additional information?	20	you asking specific to tale?
21	So I don't disagree with their opinion, I'm	21	Q. Yes. With respect to talc exposure,
22	just saying.	22	what type of talc exposure causes ovarian cancer?
23	Q. Dr. Singh, do you recommend to your own	23	MS. PARFITT: Objection. Form.
24	patients that they avoid talcum powder use?	24	A. You know, perineal application of talc
25	A. Now, I do.	25	can, you know, use of talc.
	Page 123		Page 125
1	Q. When did you begin doing that?	1	Q. What types of strike that.
2	A. Last year.	2	What types of talcum powder cause ovarian
3	Q. Do you ask them if they use talcum	3	cancer?
4	powder as part of a routine screening?	4	MS. PARFITT: Objection. Form.
5	A. In people that sorry.	5	A. So, again, I I my causal question
6	In patients that I talk about ovarian	6	was the use of talcum powder products and ovarian
7	cancer.	7	cancer. I did not disaggregate between X and Y
8	Q. Is that something that you began doing	8	and Z in terms of, you know, this type of talcum
9	over the past year?	9	powder product.
10	A. I would say sometime last year.	10	Q. What type of ovarian cancer does talcum
11	Q. What about patients with a long history	11	powder cause?
12	of use? Do you consider them at elevated risk of	12	MS. PARFITT: Objection. Form.
13	developing cancer?	13	A. Talcum powder products are, you know,
14	MS. PARFITT: Objection. Form.	14	causally linked to the development of ovarian
15	A. So I haven't thought about it that way.	15	cancer, but the link is strongest for serous
	I mean, you know, when that discussion about	16	epithelial ovarian cancer.
16			() A my other tymes of avenian companthat
17	ovarian cancer comes up, we talk about risk	17	Q. Any other types of ovarian cancer that
17 18	ovarian cancer comes up, we talk about risk factors and, you know, I recommended that.	18	you believe talcum powder causes?
17 18 19	ovarian cancer comes up, we talk about risk factors and, you know, I recommended that.  Q. Have you ever recommended prophylactic	18 19	you believe talcum powder causes?  MS. PARFITT: Objection. Form.
17 18 19 20	ovarian cancer comes up, we talk about risk factors and, you know, I recommended that.  Q. Have you ever recommended prophylactic surgery to remove the fallopian tubes and ovaries	18 19 20	you believe talcum powder causes?  MS. PARFITT: Objection. Form.  A. You know, other studies have provided,
17 18 19 20 21	ovarian cancer comes up, we talk about risk factors and, you know, I recommended that.  Q. Have you ever recommended prophylactic surgery to remove the fallopian tubes and ovaries that you think patients that you think may	18 19 20 21	you believe talcum powder causes?  MS. PARFITT: Objection. Form.  A. You know, other studies have provided, you know, causal links to borderline, you know,
17 18 19 20 21 22	ovarian cancer comes up, we talk about risk factors and, you know, I recommended that.  Q. Have you ever recommended prophylactic surgery to remove the fallopian tubes and ovaries that you think patients that you think may have had long-term exposure to talc?	18 19 20 21 22	you believe talcum powder causes?  MS. PARFITT: Objection. Form.  A. You know, other studies have provided, you know, causal links to borderline, you know, other tumors. But, you know, it's mainly the
17 18 19 20 21 22 23	ovarian cancer comes up, we talk about risk factors and, you know, I recommended that.  Q. Have you ever recommended prophylactic surgery to remove the fallopian tubes and ovaries that you think patients that you think may have had long-term exposure to talc?  MS. PARFITT: Objection. Form.	18 19 20 21 22 23	you believe talcum powder causes?  MS. PARFITT: Objection. Form.  A. You know, other studies have provided, you know, causal links to borderline, you know, other tumors. But, you know, it's mainly the epithelial ovarian cancer.
17 18 19 20 21 22	ovarian cancer comes up, we talk about risk factors and, you know, I recommended that.  Q. Have you ever recommended prophylactic surgery to remove the fallopian tubes and ovaries that you think patients that you think may have had long-term exposure to talc?	18 19 20 21 22	you believe talcum powder causes?  MS. PARFITT: Objection. Form.  A. You know, other studies have provided, you know, causal links to borderline, you know, other tumors. But, you know, it's mainly the

	Page 126		Page 128
1	MS. PARFITT: Objection. Form.	1	Q. You did not conduct a meta-analysis
2	A. I examined, you know, the causal link	2	here; is that right?
3	between talcum powder products and ovarian cancer	3	A. Yes. And I partly pragmatic
4	as the data was available in the available	4	reasons. Partly, there were so many other
5	studies. You know, I could not there was	5	meta-analyses that I, you know although I
6	no I mean, there was data on	6	would have done things a little bit differently,
7	dose-responsiveness, and we can discuss that.	7	and I just didn't feel the need for one more
8	But, you know, I don't know if it's a single	8	meta-analysis that would be informative.
9	application or it's 20 years. I mean, it is	9	Q. What was your methodology for focusing
10	regular use and that would cause it.	10	on certain studies or excluding other studies?
11	Q. It's correct that you have not	11	A. So I'm not aware that I excluded
12	evaluated specifically what dose of talcum powder	12	certain studies, because I, as I compare, I have
13	is required to cause ovarian cancer; correct?	13	included all the epidemiologic studies that are
14	MS. PARFITT: Object to form.	14	here. There's always a possibility that once,
15	A. Yeah. I mean, I don't know a specific	15	you know, when you do a review, that you may
16	dose that would cause ovarian cancer.	16	have.
17	Q. What was your methodology for	17	But, you know, I included all the relevant
18	concluding that talc causes ovarian cancer or, I	18	case-control studies and the cohort studies and
19	guess to be more precision, serous ovarian	19	the systematic review and meta-analysis that I
20	cancer?	20	identified.
21	A. Yeah. I mean, mainly	21	And, yeah, I mean, I may have weighed
22	MS. PARFITT: Objection.	22	studies differently based on their quality,
23	A. Yeah. Epithelial ovarian cancer.	23	validity and reliability.
24	Q. What was your methodology?	24	Q. That's how you tried to make a
25	A. So, yeah, I did, you know so prior	25	distinction?
	Page 127		Page 129
1	Page 127 to that, I was aware of systematic reviews and	1	Page 129 A. Yeah.
1 2		1 2	
	to that, I was aware of systematic reviews and		A. Yeah.
2	to that, I was aware of systematic reviews and other reviews in this area.	2	<ul><li>A. Yeah.</li><li>Q. Do you believe the standard for proving</li></ul>
2	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look	2	<ul><li>A. Yeah.</li><li>Q. Do you believe the standard for proving causation in the scientific literature is the</li></ul>
2 3 4	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.	2 3 4	A. Yeah. Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation?
2 3 4 5	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?	2 3 4 5	A. Yeah. Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation? MS. PARFITT: Objection. Form.
2 3 4 5 6	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?  Q. Well, if you have to. I mean, my	2 3 4 5 6	<ul> <li>A. Yeah.</li> <li>Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation?</li> <li>MS. PARFITT: Objection. Form.</li> <li>A. Yeah. I mean, the standard for</li> </ul>
2 3 4 5 6 7	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?  Q. Well, if you have to. I mean, my question was just simply: What was your	2 3 4 5 6 7	A. Yeah. Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation? MS. PARFITT: Objection. Form. A. Yeah. I mean, the standard for causation, you know, is at least I was
2 3 4 5 6 7 8 9	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?  Q. Well, if you have to. I mean, my question was just simply: What was your methodology for concluding that talc causes	2 3 4 5 6 7 8	A. Yeah. Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation? MS. PARFITT: Objection. Form. A. Yeah. I mean, the standard for causation, you know, is at least I was applying the same standard.
2 3 4 5 6 7 8 9	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?  Q. Well, if you have to. I mean, my question was just simply: What was your methodology for concluding that talc causes epithelial ovarian cancer?	2 3 4 5 6 7 8	<ul> <li>A. Yeah.</li> <li>Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation?</li> <li>MS. PARFITT: Objection. Form.</li> <li>A. Yeah. I mean, the standard for causation, you know, is at least I was applying the same standard.</li> <li>Q. Are you familiar with the FDA analysis</li> </ul>
2 3 4 5 6 7 8 9	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?  Q. Well, if you have to. I mean, my question was just simply: What was your methodology for concluding that talc causes epithelial ovarian cancer?  MS. PARFITT: Dr. Singh, anytime you	2 3 4 5 6 7 8 9	A. Yeah. Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation? MS. PARFITT: Objection. Form. A. Yeah. I mean, the standard for causation, you know, is at least I was applying the same standard. Q. Are you familiar with the FDA analysis of the Bradford Hill factors and that they have
2 3 4 5 6 7 8 9 10 11	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?  Q. Well, if you have to. I mean, my question was just simply: What was your methodology for concluding that tale causes epithelial ovarian cancer?  MS. PARFITT: Dr. Singh, anytime you need to consult your report.	2 3 4 5 6 7 8 9 10	A. Yeah. Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation? MS. PARFITT: Objection. Form. A. Yeah. I mean, the standard for causation, you know, is at least I was applying the same standard. Q. Are you familiar with the FDA analysis of the Bradford Hill factors and that they have concluded that causation is not established with
2 3 4 5 6 7 8 9 10 11 12 13	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?  Q. Well, if you have to. I mean, my question was just simply: What was your methodology for concluding that tale causes epithelial ovarian cancer?  MS. PARFITT: Dr. Singh, anytime you need to consult your report.  A. Yeah. I mean, the methodology was, you	2 3 4 5 6 7 8 9 10 11	A. Yeah. Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation? MS. PARFITT: Objection. Form. A. Yeah. I mean, the standard for causation, you know, is at least I was applying the same standard. Q. Are you familiar with the FDA analysis of the Bradford Hill factors and that they have concluded that causation is not established with respect to talc and ovarian cancer?
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2 3 4 5 6 7 8 9 10 11 12 13 14	to that, I was aware of systematic reviews and other reviews in this area.  So I, as a broad you know, we should look at the methods section of this report.  Do you want to look at the methods?  Q. Well, if you have to. I mean, my question was just simply: What was your methodology for concluding that talc causes epithelial ovarian cancer?  MS. PARFITT: Dr. Singh, anytime you need to consult your report.  A. Yeah. I mean, the methodology was, you know, gathering lines of evidence. You know, assessing for relevance, reliability and, you	2 3 4 5 6 7 8 9 10 11 12 13	A. Yeah. Q. Do you believe the standard for proving causation in the scientific literature is the same as the one that applies in litigation? MS. PARFITT: Objection. Form. A. Yeah. I mean, the standard for causation, you know, is at least I was applying the same standard. Q. Are you familiar with the FDA analysis of the Bradford Hill factors and that they have concluded that causation is not established with respect to tale and ovarian cancer? MS. PARFITT: Objection. Misstates the evidence.
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	Page 130		Page 132
1	A. Yes.	1	MS. PARFITT: Objection. Form.
2	Q. And when I say "dated," there's a stamp	2	A. So just to clarify, where do they say
3	at the top that says April 1, 2014; correct?	3	they apply the Bradford Hill in this document?
4	A. Yes.	4	Q. You're familiar with the Bradford Hill
5	Q. Have you reviewed this FDA analysis	5	criteria; is that right?
6	before today?	6	A. Yes. I use it, but in this FDA
7	A. Yes. I have reviewed the letter.	7	document, where does it state they apply the
8	Yeah.	8	Q. It is one of the criteria for
9	Q. On Page 4 of the FDA document, at the	9	consistency across studies. Is that a Bradford
10	bottom, do you see that?	10	Hill criteria?
11	A. I do.	11	A. But exactly they don't go through all
12	Q. The FDA noted that selection bias	12	of them. So I don't know if they did a Bradford
13	and/or uncontrolled confounding result in	13	Hill. So how can I just assume that? They don't
14	spurious positive associations between talc use	14	talk about, you know, specificity. They don't
15	and ovarian cancer; is that right?	15	talk about strength of association. So I can't
16	MS. PARFITT: Objection. Form.	16	assume that they're applying Bradford Hill.
17	A. Yes. That's what they conclude.	17	Q. IARC did address the Bradford Hill
18	Q. The FDA notes a lack of consistency in	18	considerations; is that right?
19	the study results; is that right?	19	A. Yes. In the year 2005. That was
20	MS. PARFITT: Objection.	20	around 15 years ago.
21	A. Yes. And this was conducted in, I	21	Q. IARC rejected classification of talc as
22	don't know, 2014, 2013.	22	carcinogenic and, instead, assigned it to the
23	Q. The FDA specifically states, "Results	23	classification of possibly carcinogenic to
24	of case-control studies do not demonstrate a	24	humans; is that right?
25	consistent positive association across studies";	25	MS. PARFITT: Objection. Misstates the
	, , , , , , , , , , , , , , , , , , ,		
	Page 131		Page 133
1	is that right?	1	evidence.
2	A. Yes. That's what they state.	2	A. So, again, you know, just clarifying
3	Q. The FDA also states that,	3	that this was done in 2005, with evidence that
4	"Dose-response evidence is lacking"; is that	4	has accumulated since then. And I wouldn't
5	right?	5	classify it I have served on IARC panels, and
6	MS. PARFITT: Objection.	6	I'm very familiar with their process. They don't
7	A. Where is that? I'm sorry.	7	reject anything. They classify drugs in the
8	Q. Look at Paragraph 3 at the bottom of	8	particular categories that they're supposed to
9	Page 4.	9	be.
10	A. Yes.	10	So it was actually classified as possibly
11	Q. The FDA further concludes that, "A	11	carcinogenic.
12	cogent biological mechanism by which tale might	12	Q. Take a look at Exhibit 20.
13	lead to ovarian cancer is lacking"; is that	13	(IARC Classifications marked
14	right?	14	Exhibit 20.)
	right?  MS. PARFITT: Objection to form.	15	BY MR. ZELLERS:
14	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the		BY MR. ZELLERS: Q. Deposition Exhibit 20 are the IARC
14 15	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the same letter, that there is, you know, the	15	BY MR. ZELLERS: Q. Deposition Exhibit 20 are the IARC classifications; is that right?
14 15 16 17 18	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the same letter, that there is, you know, the potential for talc to migrate. So, I mean, I'm	15 16	BY MR. ZELLERS: Q. Deposition Exhibit 20 are the IARC classifications; is that right? I'm sorry. Did you answer the question?
14 15 16 17	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the same letter, that there is, you know, the potential for talc to migrate. So, I mean, I'm just trying to be that's what I reviewed.	15 16 17 18 19	BY MR. ZELLERS: Q. Deposition Exhibit 20 are the IARC classifications; is that right?
14 15 16 17 18	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the same letter, that there is, you know, the potential for talc to migrate. So, I mean, I'm	15 16 17 18	BY MR. ZELLERS: Q. Deposition Exhibit 20 are the IARC classifications; is that right? I'm sorry. Did you answer the question?
14 15 16 17 18 19 20 21	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the same letter, that there is, you know, the potential for talc to migrate. So, I mean, I'm just trying to be that's what I reviewed.  Yes, it does say that there's no biological mechanism.	15 16 17 18 19 20 21	BY MR. ZELLERS:  Q. Deposition Exhibit 20 are the IARC classifications; is that right?  I'm sorry. Did you answer the question?  A. Yes. Sorry.  Q. That's okay.  A. Yes.
14 15 16 17 18 19	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the same letter, that there is, you know, the potential for talc to migrate. So, I mean, I'm just trying to be that's what I reviewed.  Yes, it does say that there's no biological	15 16 17 18 19 20	BY MR. ZELLERS:  Q. Deposition Exhibit 20 are the IARC classifications; is that right?  I'm sorry. Did you answer the question?  A. Yes. Sorry.  Q. That's okay.
14 15 16 17 18 19 20 21	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the same letter, that there is, you know, the potential for talc to migrate. So, I mean, I'm just trying to be that's what I reviewed.  Yes, it does say that there's no biological mechanism.	15 16 17 18 19 20 21	BY MR. ZELLERS:  Q. Deposition Exhibit 20 are the IARC classifications; is that right?  I'm sorry. Did you answer the question?  A. Yes. Sorry.  Q. That's okay.  A. Yes.
14 15 16 17 18 19 20 21	right?  MS. PARFITT: Objection to form.  A. Yeah. But it also concludes, in the same letter, that there is, you know, the potential for talc to migrate. So, I mean, I'm just trying to be that's what I reviewed.  Yes, it does say that there's no biological mechanism.  Q. You reviewed or strike that.	15 16 17 18 19 20 21 22	BY MR. ZELLERS: Q. Deposition Exhibit 20 are the IARC classifications; is that right? I'm sorry. Did you answer the question? A. Yes. Sorry. Q. That's okay. A. Yes. Q. All right. It lists out, starting with

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	Page 134		Page 136
1		1	
1	Q. There are 120 agents that have been	1	A. Yes.
2	determined by IARC, the International Agency for	2	Q. So out of the 1,000 agents that IARC
3	Research on Cancer, as Group 1 agents,	3	has reviewed, it has placed only one agent in
4	carcinogenic to humans; is that right?	4	Group 4, probably not carcinogenic; is that
5	A. Yeah. That includes asbestos, many	5	right?
6	others.	6	A. Yeah. But 499 are not classifiable as
7	Q. That is the only category in which IARC	7	it relates, so.
8	finds sufficient evidence in humans; correct?	8	Q. IARC doesn't even have a Group 5, not
9	A. No. To clarify, they have it may be	9	carcinogenic, does it?
10	in my report, that they have a particular way of	10	A. Well, I mean, all the once it's
11	defining that category. And it may not be just	11	probably not carcinogenic, it's not carcinogenic.
12	sufficient evidence in humans. They may be	12	Q. The best that IARC can state is that an
13	something else. If I can look back at my report.	13	agent is probably not carcinogenic to humans,
14	Q. Well, if it's in your report, it's in	14	which is Group 4; is that right?
15	your report. And we can all read that.	15	A. Yes.
16	My question to you is: Group 1 is a	16	MS. PARFITT: Objection.
17	category where IARC has determined that there is	17	Q. All right. As with strike that.
18	sufficient evidence in humans to classify an	18	With genital talc, the IARC group 2B
19	agent as carcinogenic; is that right?	19	designation is based on limited evidence in
20	MS. PARFITT: Objection. Misstates	20	humans; is that right?
21	Dr. Singh's testimony.	21	MS. PARFITT: Objection.
22	A. I mean, do I get time to	22	A. Yes. There was some animal
23	Q. Doctor, I only have seven hours here.	23	consideration. There were some biological
24	So go to Exhibit 20. I'll make this quick.	24	mechanisms, but, again, in 2005, and as I state
25	Do you see Exhibit 20 in front of you?	25	in my report, which I have, and there have been
	Page 135		Page 137
1	A. Yeah.	1	multiple studies since then. And that, you know,
2	Q. This is the IARC classifications; is	2	that they should be revisited.
3	that right?	3	Q. That means IARC cannot rule out chance,
4	A. Okay. Mm-hmm.	4	bias or confounding with reasonable confidence;
5	Q. Group 1 states, "Carcinogenic to	5	correct?
6	humans."	6	A. Based on the data they had at that
7	A. Yes.	7	time.
8	Q. Do you see that?	8	Q. What else is in 2B, possibly strike
9	A. Yeah.	9	that.
10	Q. All right. Group 2A, there are 82	10	What else is in class 2B, possibly
11	agents that are probably carcinogenic to humans;	11	carcinogenic? Are you familiar with Ginkgo
12	is that right?	12	biloba?
13	A. Yes.	13	MS. PARFITT: Objection to form.
14	Q. IARC is certainly capable of reaching a	14	A. I know the name.
15	decision that something is a known or probable	15	Q. Are you aware that that's classified as
16	carcinogen; is that right?	16	a 2B agent by IARC?
17	MS. PARFITT: Objection.	17	A. I don't know. I mean, you know, they
18	A. Yes. I mean, 15 years ago, yes, based	18	also classify as it relates to exposure. So I
19	on the evidence.	19	haven't reviewed Ginkgo biloba to be able to
20	Q. It has placed at least 200 agents in	20	answer the question.
	Group 1 or Group 2A; is that right?	21	Q. Pickled vegetables, 2B; is that right?
21			A II 1 II 0 C1
21 22	A. Yes.	22	A. How do I know? Show me.
21 22 23	<ul><li>A. Yes.</li><li>Q. There's only one agent in Group 4,</li></ul>	23	Q. Occupational
21 22	A. Yes.	1	

35 (Pages 134 to 137)

#### Page 138 Page 140 1 aware of that? 1 Q. Doctor, I'm asking you questions. 2 2 My question is: Epidemiologists consider a A. Again, this is 2015. And, you know, 3 3 yes. I don't know I'm aware of that. I mean, 1.3 odds ratio in case-control studies to be a you can't put words in my mouth that pickle --4 weak or modest association; correct? 4 5 5 MS. PARFITT: Objection. Misstates the how do I know that? 6 O. There's no chance of my putting words 6 evidence and the science. A. Not the epidemiologists that I 7 in your mouth. IARC can change its 7 8 classification for a substance; is that right? 8 contacted. You know, we look at various, you A. It does. I mean, from what I 9 know -- as I state in my report, you know, you 9 10 can have modest associations and you can have a 10 understand. 11 11 Q. It has not changed its Group 2B relative risk of one that are lower, and if you 12 classification since it determined that talc was 12 go to a low-prevalence population, and then 13 a 2B agent; is that right? 13 remove competing risk factors, those can be 14 MS. PARFITT: Objection. Form. 14 attenuated. A. It has not carried out an assessment 15 15 So the epidemiologists that I interact with, 16 and we don't look at this as weak or modest or 16 since 2005, that I'm aware of. 17 17 high. We just look at it in the whole causal Q. Has IARC changed its group 2B 18 classification? 18 framework. Q. Can you point to any peer-reviewed 19 19 A. No --MS. PARFITT: Objection. 20 20 literature on talc and ovarian cancer that states 21 21 A. -- and as far as I'm aware, no that 1.3 odds ratio is a strong association? A. Again, that's not -- I'm not looking at 22 22 assessment has been carried out. 23 23 Q. Bradford Hill, strength of association tale at 1.3 is a strong association. I'm stating 24 is one of the criteria; is that right? 24 that, yeah, I can't point to the talc literature 25 A. I don't consider them criteria. 25 that states that. Page 139 Page 141 1 There's overviews. I think -- I'm just picking Q. IARC does not refer to this as a strong 1 2 the terms. I mean, they're overviews of Bradford 2 association; correct? 3 Hill. Doesn't list them as criteria, because 3 MS. PARFITT: Objection. Form. A. I don't know what -- the particular 4 criteria implies a list of things that you can 4 5 5 pick and choose from. objective or qualifier they use. I mean --Q. You would call them what? 6 Q. FDA doesn't refer to this as a strong 6 association, do they? 7 A. Overviews. Actually, that's what he 7 8 8 MS. PARFITT: Objection to form. 9 9 A. Again, you have to sort of just show me Q. Overviews. Strength of association is 10 a Bradford Hill overview; is that right? 10 where they are, and I'll agree with it. Q. Have you seen any statement from IARC 11 11 that there is a strong association between 12 Q. Epidemiologists consider a 1.3 odds 12 ratio in case-control studies to be a weak or 13 genital talc use and ovarian cancer? 13 14 modest association; is that right? 14 A. I don't recall that particular phrase. 15 MS. PARFITT: Objection. Misstates the 15 Q. All right. The National Cancer 16 16 Institute doesn't refer to this as a strong evidence. 17 A. No. I mean, again, strength of 17 association: correct? 18 association based on -- depends on the study 18 MS. PARFITT: Objection to form. 19 question at hand, the study design, and, you 19 A. I don't recall that particular 20 know, the quality of the underlying data. So 20 objective. 21 strength of association, in and of itself, does 21 Q. Do your opinions on strength of 22 not provide any -- any -- any sort of -- any 22 association apply equally to all forms of ovarian 23 answer to the causal question. Again, I'll go 23 cancer? 24 back to my report, because I have to go back to 24 MS. PARFITT: Objection. Form. 25 25 A. Again, I'm -- you know, my opinions are my report.

	Page 142		Page 144
1	not again, we can parse this out. I mean, I	1	me when you have that.
2	was just looking at the causal question. Is talc	2	A. Yeah.
3	causally related to the development of ovarian	3	Q. "Proposal to research community." Do
4	cancer?	4	you see that?
5	And, you know, most of the evidence that I	5	A. Yes.
6	examined were was provided in terms of serous	6	Q. Tell me if I read this statement by the
7	epithelial cancer, and	7	authors correctly.
8	Q. I thought you told me that your	8	"The current body of experimental and
9	methodology was to look at the Bradford Hill	9	epidemiological evidence is insufficient to
10	overview factors; is that right?	10	establish a causal association between perineal
11	A. Yeah.	11	use of talc and ovarian cancer risk.
12	Q. All right. And one of those factors is	12	Experimental research is needed to better
13	strength of association; is that right?	13	characterize deposition, retention, and clearance
14	A. Yes.	14	of talc to evaluate the ovarian carcinogenicity
15	Q. And that's a factor that you looked at;	15	of tale."
16	correct?	16	Did I read that correctly?
17	A. Yes.	17	A. Yes.
18	Q. Do your opinions on strength of	18	Q. You're drawing conclusions from this
19	association apply equally to all forms of ovarian	19	study that are broader than the study authors'
20	cancer?	20	own conclusions; is that right?
21	MS. PARFITT: Objection. Form.	21	MS. PARFITT: Objection.
22	A. Well, I did not disaggregate my, you	22	A. I didn't draw. So you were asking me
23	know, opinion by histologic subtype.	23	that whether I drew a single conclusion from the
24	Q. You cite to the Langseth paper; is that	24	Langseth. I mean, there are I think I cite
25	right?	25	all the meta-analyses first, and then so I'm
	Page 143		Page 145
1	A. I do.	1	not just drawing inferences from there.
2	Q. You state that the authors in Langseth	2	And the authors, as far as I am aware, A,
3	2008 found an odds ratio ranging between 1.12 to	3	there have been several other studies published
4			
	1.4, depending upon the type of study design. Is	4	since then. This is 2007. So we have 12 years
5	1.4, depending upon the type of study design. Is that right? This is on Page 22 of your report.	l .	since then. This is 2007. So we have 12 years and several publications. And B. the authors
5 6	that right? This is on Page 22 of your report.	5	and several publications. And, B, the authors
6	that right? This is on Page 22 of your report.  A. Okay.	5 6	and several publications. And, B, the authors themselves have provided opinions that they are
6 7	that right? This is on Page 22 of your report.  A. Okay.  Q. Langseth, in fact, rejects causation	5 6 7	and several publications. And, B, the authors themselves have provided opinions that they are causally related. Dr. Siemiatycki, as far as I'm
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37 (Pages 142 to 145)

	Page 146		Page 148
1	A. This is not the only	1	overall evidence, my testimony is that the cohort
2	MS. PARFITT: Objection. Form.	2	study estimates are in line with the case-control
3	A paper. I cited on 2017, 2018.	3	evidence and provide evidence of consistency.
4	Q. Go to the acknowledgments section.	4	Q. The cohort studies themselves, looking
5	Do you see the acknowledgments off to the	5	just at those studies, and I'm going to ask you
6	left?	6	about the others
7	A. Yes.	7	A. Sure, sure.
8	Q. The authors are IARC members; is that	8	Q do not show a consistent
9	right?	9	association between talc use and ovarian cancer;
10	A. Yes.	10	correct?
11	Q. The authors of this paper, Langseth?	11	MS. PARFITT: Objection. Misstates the
12	A. Yes.	12	testimony.
13	Q. Another overview factor of Bradford	13	A. So that's not the way I look at
14	Hill is consistency; is that right?	14	evidence. I look at everything. That's what you
15	A. Yes.	15	want to look at. You can look at it.
16	Q. The literature does not show a	16	I just look at evidence, you know, whatever
17	consistent association between talc use and	17	is out there. So I didn't look at cohort studies
18	ovarian cancer; right?	18	in and of themselves.
19	MS. PARFITT: Objection to form.	19	And that's why we do systematic reviews.
20	A. I disagree.	20	That's why we do meta-analyses, because you want
21	Q. The cohort studies do not show an	21	to look at everything at the same time.
22	association between talc use and ovarian cancer;	22	Q. You did not look at the cohort studies
23	correct?	23	individually; correct?
24	MS. PARFITT: Objection to form.	24	A. I did. And they're in my report.
25	A. I disagree. The cohort studies show	25	Q. If you looked at the cohort studies
	Page 147		Page 149
1	Page 147 significant you know, increased risk, which is	1	
1 2		1 2	Page 149 individually, they do not show a consistent association between talc use and ovarian cancer;
	significant you know, increased risk, which is in the same direction as the case-control		individually, they do not show a consistent
2	significant you know, increased risk, which is in the same direction as the case-control studies, which, as several of the authors, such	2	individually, they do not show a consistent association between talc use and ovarian cancer;
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2 3 4	significant you know, increased risk, which is in the same direction as the case-control studies, which, as several of the authors, such as Penninkilampi and others and me, interpret as	2 3 4	individually, they do not show a consistent association between talc use and ovarian cancer; correct?  MS. PARFITT: Objection. Misstates the
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38 (Pages 146 to 149)

	_	1	
	Page 150		Page 152
1	ovarian cancer in one of them, and cumulative	1	MS. PARFITT: Wait. Are you in the
2	evidence from cohort studies shows an excess risk	2	middle?
3	of ovarian cancer which is not statistically	3	A. Yeah. That's incorrect. It should be
4	significant.	4	the population-based case studies. That's my
5	Q. Hospital-based, case-control studies	5	you know, that's a misstatement on my part.
6	collectively do not show an association between	6	Q. So you need to amend your report?
7	talc use and ovarian cancer; correct?	7	A. Yeah. Yeah.
8	MS. PARFITT: Objection. Misstates the	8	Q. So if we go to Page 54
9	evidence.	9	A. Yeah.
10	A. That is incorrect, because	10	Q Paragraph 8, you state that it's an
11	hospital-based, case-control studies also show an	11	error when you state, "As opposed to
12	association between talc use and ovarian cancer	12	hospital-based controls, which may be less
13	which is not, you know and I would have to	13	susceptible to selection bias, the
14	look again. Please bring out the studies,	14	population-based, case-control studies have
15	because I want to look at some of the studies	15	consistently showed a higher estimate of
16	before I, you know, provide specific you're	16	increased risk of ovarian cancer associated with
17	asking very specific questions about	17	talc use."
18	hospital-based studies, so I have to look at the	18	A. Yeah. And I was applying the less
19	studies.	19	susceptible to the population-based statement.
20	Q. If you can't answer a question, tell me	20	Q. How do you need to correct this
21	you can't answer it. But my question is,	21	statement?
22	hospital-based, case-control studies collectively	22	A. I don't know how, you know. Yeah, it
23	do not show an association between talc use and	23	would be as opposed to hospital-based controls,
24	ovarian cancer; correct?	24	population-based, case-control studies may be
25	MS. PARFITT: Objection. Misstates the	25	less susceptible to selection bias.
	Page 151		Page 153
1	evidence.	1	Q. You believe that population-based
2	A. No. I disagree. And, again, I'd have	2	studies may be susceptible to less selection
3	to can we pull the Penninkilampi paper?	3	bias?
4	Q. Doctor, I'm going to ask you about that	4	A. May be less susceptible.
5	paper.	5	Q. Take a look at Exhibit 21. That's the
6	A. No. But then how can I answer	6	article we looked at a few minutes ago.
7	questions?	7	Do you see that?
8	Q. I need you to answer my questions.	8	A. That's the Langseth?
9	If you can't answer a question, then tell me	9	Q. Yes. The Langseth article.
10	you can't answer the question.	10	Do you see that?
11	A. I'm willing to answer the question.	11	A. Yes.
12	Just bring me the evidence so that I can look at	12	Q. Take a look under the hospital-based
13	it.	13	studies.
14	I'm sorry. I'm trying my best.	14	Do you see that on Page 359?
15	Q. In your report, you state that	15	A. Yes.
16	hospital-based, case-control studies may be less	16	Q. You are the one who cites this paper
17	susceptible to selection bias than	17	and relies on it; is that right?
18	population-based, case-control studies; correct?	18	A. Yes.
19	A. Where do I state that?	19	Q. If we look at pooled odds ratio for
20	Q. Look at your report on Page 54,	20	hospital-based studies
	Paragraph 8.	21	A. Mm-hmm.
21		22	Q the odds ratio is 1.2 and the
22	A. Actually, I state entirely the		-
22 23	opposite. I state that the population-based	23	confidence interval is a .92 to 1.36; is that
22			-

39 (Pages 150 to 153)

	Page 154		Page 156
1	Q. That means that it may or may not be	1	behavioral change bias, which attenuates towards
2	show an association between talc use and ovarian	2	the null. It induces an element of
3	cancer. The pooled result; is that right?	2 3 4 5 6	misclassification of exposure, which goes towards
4	MS. PARFITT: Objection to form.	4	null. It limits the duration of assessment,
5	Q. Given that confidence interval.	5	which, you know, limits assessment. So it
6	MS. PARFITT: Objection to form.	6	doesn't have power to suggest.
7	A. Yeah. Again, this is you know, at	7	So, yes, recall bias is a feature that is
8	that time. I don't know what studies have been	8	better assessed in the cohort studies, but recall
9	added. We can look in the new paper, which I'm	9	bias, for exposures that are daily use, such as
10	not sure why it's not been brought up.	10	talc, are less likely, you know, to be in play.
11	But, yes, it does show an excess risk, not	11	Recall bias let me finish my explanation.
12	statistically significant, consistent with the	12	Recall bias would less likely be in play
13	population studies.	13	because we don't see evidence with nonperineal
14	Q. All right. Hospital-based control	14	talc exposure. Recall bias are less likely to be
15	studies, you're more likely to be comparing	15	in play because we only see it with epithelial
16	hospitalized patients to hospitalized patients;	16	ovarian cancer.
17	is that right?	17	So, yes, cohort studies less, but there are
18	A. Yes. That's why they're hospital	18	other biases.
19	based.	19	Q. Couldn't recall bias explain the
20	Q. Population-based studies, you're more	20	difference between cohort studies and
21	likely to be comparing ill people to healthy	21	retrospective case-control studies?
22	people; is that right?	22	MS. PARFITT: Objection. Form.
23	A. Yeah. Your source of control. I	23	A. I don't think so. There's multiple
24	mean well, it depends. How do you know if	24	other biases and multiple other strengths and
25	it's ill people? If you are sourcing from the	25	limitations that would have to be considered.
	Page 155		Page 157
1	Page 155 population in both, it's a population-based	1	Q. You cite to Berge, a 2017 paper, in
1 2	population in both, it's a population-based study.	1 2	
	population in both, it's a population-based study.  Q. Population-based, case-control studies,		Q. You cite to Berge, a 2017 paper, in your report; is that right? Is that correct?  A. Yes.
2	population in both, it's a population-based study.  Q. Population-based, case-control studies, the ones that you look at only show a weak	2	Q. You cite to Berge, a 2017 paper, in your report; is that right? Is that correct?  A. Yes.  MR. ZELLERS: Take a look at
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40 (Pages 154 to 157)

	Page 158		Page 160
1	Q. What was your methodology for	1	that the case-control stories are more powered.
2	discounting the effect of recall bias in the	2	Q. Do you agree that some case-control
3	population-based, case-control studies?	3	studies have shown statistically significant
4	A. I mean, it's not like there's a once	4	findings and others have not?
5	recall is operational, there are no methods that	5	A. Yes.
6	you can and do discount. But just the quality	6	Q. What is your methodology for weighing
7	and, you know, the quantity of evidence over	7	the lack of consistency in statistical
8	studies and the fact that even the cohort	8	significance across studies?
9	studies, despite these limitations, show an	9	MS. PARFITT: Objection. Form.
10	increased risk suggests that recall bias, while	10	A. I can answer that. Yeah.
11	it is potential, cannot explain be the only	11	So the methodology for correcting the lack
12	explanation for a causal link between talc and	12	of significance, that's why you do a
13	ovarian cancer. You cannot adjust for recall	13	meta-analysis. That's an inverse variance
14	bias after the completion of the study.	14	weighted meta-analysis. You so all of these
15	Q. What is the rate of error in that	15	studies have accounted for the fact that their
16	methodology?	16	confidence intervals are crossing 1. And that's
17	A. I think that none of them have	17	how they have accounted for lack of a statistical
18	calculated it. And Dr. Cramer has done in his	18	significance.
19	last study. And it appears that you'd have to	19	So you can see that all of these estimates
20	need a significant degree of recall bias. And I	20	are weighted by sample size. So
21	am going to reference my report.	21	Q. Do you agree that if a study does not
22	Q. Okay. Didn't the cohort studies	22	show a statistically significant association, it
23	involve a much greater	23	could mean that no risk exists? Correct?
24	A. I'm not done.	24	MS. PARFITT: Objection. Form.
25	MS. PARFITT: Excuse me.	25	A. In the context of that study. But,
	Page 159		Page 161
1	Page 159 A. I'm done.	1	
1 2		1 2	again, I am looking at the cumulative evidence.
	A. I'm done.		
2	A. I'm done.  MS. PARFITT: One moment. He wanted to	2	again, I am looking at the cumulative evidence.  Q. It could mean strike that.
2	A. I'm done.  MS. PARFITT: One moment. He wanted to reference something in his report.	2 3	again, I am looking at the cumulative evidence.  Q. It could mean strike that.  It could just be occurring by chance; is
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	Page 162		Page 164
1	statistically significant increased risk of total	1	Study questionnaire; correct?
2	epithelial ovarian cancer; is that right?	2	A. Yes.
3	A. Let me just look at it. There's so	3	Q. And you cite that on Page 48 of your
4	many of these. Yes.	4	report, second paragraph; is that right?
5	Q. The Gates 2008 study used data	5	A. Yes.
6	collected in the Nurses' Health Study; is that	6	Q. You state, "Further, as discussed
7	right?	7	above, determining never use, based only on a
8	A. Yes. There was another part to it as	8	one-time question, near the start of the study,
9	well.	9	14 years prior to terminating the study in 1996,
10	Q. In the Nurses' Health Study, the	10	introduces undirectional behavioral change bias,
11	participants were asked about their talc exposure	11	likely misclassifying some ever users who used
12	in one questionnaire in 1982; is that right?	12	talc during the study as never users and biased
13	A. Yes.	13	the findings toward the null."
14	Q. When they were asked about their talc	14	Is that what you state in your report?
15	use, the participants were between 36 and 61	15	A. Let me just read it. Yes.
16	years of age; is that right?	16	Q. So when you discuss the Gertig 2000
17	A. Yes.	17	study, you say that, because the participants in
18	Q. As you state in your report, you agree	18	the Nurses' Health Study were only about or only
19	that, although talc exposure and I'm looking	19	asked about talc use once, near the beginning of
20	at Page 41	20	the study, women who started using talc after
21	A. Yes.	21	they completed that questionnaire could have been
22	Q. The first paragraph. You agree that,	22	misclassified as never users; is that right?
23	"Although talc exposure was only measured in the	23	A. Yeah.
24	1982 Nurses' Health Study questionnaire, when	24	Q. But when you talk about the study that
25	participants were between 36 to 61 years of age,	25	you believe supports your opinion
	Page 163		Page 165
1	the number of users who began talc use after this	1	A. Yeah.
2	is likely small, as shown by the fact that more	2	Q Gates 2008, you recognize that the
3	than 95 percent of controls with regular talc in	3	vast majority of women who use talc initiate use
4	the NECC reported talc use before age 35."	4	before age 36; is that right?
5	A. Yes.	5	A. Yeah. But it does not both points
6	Q. Is that correct?	6	are valid. I mean, I'm just stating the
7	A. Yes.	7	limitations of the Gates study and the Gates
8	Q. Later in your report, on Pages 47 and	8	analysis. So.
9	48, you discuss the Gertig 2000 study; is that	9	I don't see an incongruity that you're
10	right?	10	trying to point out. I'm just saying the
11	A. Yes.	11	proportion of women who were never users, the
12	Q. That study also uses the data from the	12	number of users who began is likely small. But
13	Nurses' Health Study; correct?	13	it still does not eliminate the possibility of
14	A. Yes. It's all part of the same cohort.	14	unidirectional behavioral change bias.
		15	Q. When you're looking at a cohort study,
15	Q. That study, Gertig 2000, did not find a	1 13	
15 16	Q. That study, Gertig 2000, did not find a statistically significant relationship between	16	Gertig 2000 that does not support your opinion,
			you're talking about limitations; correct?
16 17 18	statistically significant relationship between	16	
16 17	statistically significant relationship between daily talc use and all types of ovarian cancer;	16 17	you're talking about limitations; correct?
16 17 18	statistically significant relationship between daily talc use and all types of ovarian cancer; is that right?	16 17 18	you're talking about limitations; correct?  MS. PARFITT: Objection. Misstates his
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16 17 18 19 20 21	statistically significant relationship between daily talc use and all types of ovarian cancer; is that right?  A. Yeah. Again, I mean, they are different they're the same cohort with different follow-up time, different design. But	16 17 18 19 20 21	you're talking about limitations; correct?  MS. PARFITT: Objection. Misstates his testimony.  A. I'm not talking about a study that does not support mine. I'm looking at the strengths
16 17 18 19 20 21 22	statistically significant relationship between daily talc use and all types of ovarian cancer; is that right?  A. Yeah. Again, I mean, they are different they're the same cohort with different follow-up time, different design. But it did not. And it found an increased risk for	16 17 18 19 20 21 22	you're talking about limitations; correct?  MS. PARFITT: Objection. Misstates his testimony.  A. I'm not talking about a study that does not support mine. I'm looking at the strengths and limitations of a study.

	Page 166		Page 168
1	MS. PARFITT: Objection. Misstates his	1	participants in the Houghton 2014 study was 63.3
2	testimony.	2	years at baseline, with 12.4 years of follow-up
3	A. I am not.	3	on average; is that right?
4	First of all, they are two different	4	A. Yes.
5	analyses of a cohort. So they're not two	5	Q. And then you say that, because
6	different things about.	6	participants were not asked again about talcum
7	And I'm pointing out, you know, the reasons	7	powder use during follow-up, people who initiated
8	that that so I'm, you know, pointing out in	8	talc use after the study began were being
9	Gates that, yes, talc exposure is a single-time	9	misclassified as never users. Is that right?
10	exposure. And it is you know, introduces an	10	A. Yes.
11	element of bias.	11	Q. So, again, when the study supports your
12	But I'm also pointing out in Gates why that	12	opinion, you recognize that the vast majority of
13	bias is likely to be, you know, small coming from	13	perineal talc users begin that use well before
14	the other consortium.	14	age 63.
15	Q. But you don't say that when you discuss	15	MS. PARFITT: Objection. Misstates
16	Gertig 2000, do you?	16	testimony.
17	A. Yeah. Because it wasn't done in	17	A. I don't recognize that. How do I
18	conjunction with the NECC consortium.	18	recognize that? I'm just citing that, in Gates,
19	Q. All right. Look at Page 49 of your	19	they provided that opinion. Yeah.
20	report. You discuss the Houghton 2014 study; is	20	In the Gates study, they quoted data from
21	that right?	21	the NECC, that that's one study that provides. I
22	A. Yes.	22	don't know what's happening in the in this
23	Q. All right. Houghton did not find a	23	Houghton study, that vast majority. That's
24	statistically significant increase in the risk of	24	something that you are providing. And you
25	ovarian cancer with perineal talc use; is that	25	provide data that the vast majority of users
	Page 167		
	Page 107		Page 169
1		1	
1 2	right? A. Yes.	1 2	began
	right? A. Yes.	1	began Q. It's something you cited in your
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43 (Pages 166 to 169)

	Page 170		Page 172
1	and both are entirely congruent with each other.	1	MR. ZELLERS: So I'll ask just a few
2	But yes	2	questions about this study
3	Q. Tell	3	MS. PARFITT: And if it's not here
4	A. Yes.	4	MR. ZELLERS: then we'll take a
5	Q. Are you finished?	5	break, because we've been going for a while.
6	A. Yes.	6	(Article entitled "Perineal Talc
7	Q. All right. On what are you relying to	7	Use and Ovarian Cancer, A Systematic Review
8	opine that enough women begin talcum powder use	8	and Meta-Analysis" marked Exhibit 23.)
9	in their 50s and 60s such that the results of	9	BY MR. ZELLERS:
10	Houghton or Gates 2000 are biased toward the	10	Q. Doctor
11	null?	11	A. I think we need a break in five
12	A. Well, I mean, we know exactly. I	12	minutes. I need a break. I don't know about
13	mean, we don't know that. I mean, we can't	13	you.
14	even a small amount, and that's important to	14	Q. We don't want to wear you out.
15	know, that even a small amount of users was	15	A. It's only half. Not even half the way.
16	class because we didn't ask those questions.	16	Q. I'm handing you Exhibit 23. This is
17	So even a small amount of users who had moved to	17	the Penninkilampi meta-analysis that you have
18	the other category would have nullified you	18	referred to in your report and also in your
19	know, would have biased it towards the null.	19	testimony; is that right?
20	Q. Based on all your review, the data that	20	A. Yes.
21	you came across and that you cite in your report,	21	Q. You rely on this meta-analysis,
22	are that the vast majority of women begin talc	22	Deposition Exhibit 23, in forming your opinions;
23	use in their 20s or earlier; correct?	23	is that right?
24	A. No. I cite that in the NECC. That's	24	A. As one of the studies. Yes.
25	the data I came across. And that's why it is	25	Q. It's a 2018 meta-analysis; is that
	Page 171		Page 173
1	cited. So to mischaracterize it as not being	1	right?
2	cited is incorrect.	2	A. Yes.
3	Q. What is the latency period for ovarian	3	Q. Are you aware that this meta-analysis
4	cancer?	4	by Penninkilampi does not include the Gates 2010
		1 -	by I chilinking aces not merade the Sates 2010
5	A. I don't know a specific number. It's,	5	update of the Nurses' Health Study?
5 6	A. I don't know a specific number. It's, you know, several years.		
		5	update of the Nurses' Health Study?
6	you know, several years.	5 6	update of the Nurses' Health Study?  A. When you say the Gates 2002 the
6 7	you know, several years.  Q. Several years.	5 6 7	update of the Nurses' Health Study?  A. When you say the Gates 2002 the study that we
6 7 8	you know, several years. Q. Several years. That's your testimony based upon all of the	5 6 7 8	update of the Nurses' Health Study?  A. When you say the Gates 2002 the study that we  Q. What we looked at before was Gates 2008. And we also looked at Gertig 2000  A. All these different studies.
6 7 8 9	you know, several years. Q. Several years. That's your testimony based upon all of the data and material you've reviewed?	5 6 7 8 9	update of the Nurses' Health Study?  A. When you say the Gates 2002 the study that we  Q. What we looked at before was Gates 2008. And we also looked at Gertig 2000
6 7 8 9 10	you know, several years. Q. Several years. That's your testimony based upon all of the data and material you've reviewed? A. Yes. I mean	5 6 7 8 9	update of the Nurses' Health Study?  A. When you say the Gates 2002 the study that we  Q. What we looked at before was Gates 2008. And we also looked at Gertig 2000  A. All these different studies.
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44 (Pages 170 to 173)

	Page 174		Page 176
1	referred to as Gertig 2000?	1	So I think it's quite reliable and, you
2	A. Yeah. I have. It's cited in my report	2	know, they were justified. They said we're going
3	as well, 92.	3	to look at case control with more than 50 cases.
4	Q. Are you aware that Penninkilampi does	4	So I don't consider it unreliable for that
5	not include the Gates 2010 update of the Nurses'	5	reason.
6	Health Study?	6	MR. ZELLERS: Let's take a break.
7	MS. PARFITT: Refer to your	7	THE VIDEOGRAPHER: Here ends Media
8	A. Can I take a look?	8	No. 2. Off the record, 12:24 p.m.
9	MS. PARFITT: Of course, you can.	9	(Lunch recess was taken.)
10	Q. Sure.	10	THE VIDEOGRAPHER: Here begins media
11	A. Yeah. It cites Gertig.	11	No. 3 in today's deposition of Sonal Singh, MD,
12	Q. But it does not cite Gates 2010; is	12	M.P.H. Back on the record, 1:02 p.m.
13	that right?	13	BY MR. ZELLERS:
14	A. I don't see it.	14	Q. Dr. Singh, another Bradford Hill
15	Q. Do you weigh this study, the	15	overview factor that you considered is
16	meta-analysis by Penninkilampi, less because it	16	dose-response; is that right?
17	does not include the Gates 2010 study?	17	A. Yes.
18	A. I mean, all of these meta-analyses,	18	Q. Which studies show a dose-response?
19	most of them have found, you know, similar odds	19	A. Let me just refer to my report.
20	ratio. You know, some of them have made	20	So in you know, in assessing
21	different decisions.	21	dose-response, it's very challenging with an
22	They have made for example, they made	22	exposure such as perineal talc, particularly
23	decisions about more than 50 cases. Other if	23	because, you know, you need to know the amount,
24 25	you look at the Taher meta-analysis, they	24	you need to know the duration, you need to know
25	decided, based on that a New Castle Tawas	25	the intensity of exposure. So there are
	Page 175		Page 177
1	Skill Rating will include studies.	1	challenges.
2	So you have to review that. Just because	2	The second is the challenge of modeling
3	they excluded Gates 2010, I wouldn't weigh it	1 2	1 3371 1
4		3	dose-response. When we say dose-response or
1 -	differently. That's my answer.	4	exposure outcome, is it linear monotonic
5	differently. That's my answer.  Q. Gates 2010 tends to negate an		
	Q. Gates 2010 tends to negate an association between perineal talc use and ovarian	4	exposure outcome, is it linear monotonic relationships?  And, you know, several studies, some measure
5 6 7	Q. Gates 2010 tends to negate an association between perineal talc use and ovarian cancer; correct?	4 5	exposure outcome, is it linear monotonic relationships?  And, you know, several studies, some measure duration, some measure intensity, some measure
5 6 7 8	Q. Gates 2010 tends to negate an association between perineal talc use and ovarian cancer; correct?  MS. PARFITT: Objection. Misstates the	4 5 6 7 8	exposure outcome, is it linear monotonic relationships?  And, you know, several studies, some measure duration, some measure intensity, some measure duration and frequency. So as I cite in my
5 6 7 8 9	Q. Gates 2010 tends to negate an association between perineal talc use and ovarian cancer; correct?  MS. PARFITT: Objection. Misstates the evidence.	4 5 6 7 8 9	exposure outcome, is it linear monotonic relationships?  And, you know, several studies, some measure duration, some measure intensity, some measure duration and frequency. So as I cite in my dose-response section, which I'm trying to
5 6 7 8 9	Q. Gates 2010 tends to negate an association between perineal talc use and ovarian cancer; correct?  MS. PARFITT: Objection. Misstates the evidence.  A. So negates the evidence? I mean, in	4 5 6 7 8 9	exposure outcome, is it linear monotonic relationships?  And, you know, several studies, some measure duration, some measure intensity, some measure duration and frequency. So as I cite in my dose-response section, which I'm trying to find I'm sorry yeah, Page 56 of my report.
5 6 7 8 9 10 11	<ul> <li>Q. Gates 2010 tends to negate an association between perineal talc use and ovarian cancer; correct?</li> <li>MS. PARFITT: Objection. Misstates the evidence.</li> <li>A. So negates the evidence? I mean, in fact, if you look at influence analyses conducted</li> </ul>	4 5 6 7 8 9 10	exposure outcome, is it linear monotonic relationships?  And, you know, several studies, some measure duration, some measure intensity, some measure duration and frequency. So as I cite in my dose-response section, which I'm trying to find I'm sorry yeah, Page 56 of my report.  Q. Which studies show a dose-response?
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45 (Pages 174 to 177)

	Page 178		Page 180
1	A. Yes, I do.	1	Q. On 337, there's a table that shows the
2	Q. On what page?	2	risk of ovarian cancer for women who used talc
3	A. Just give me a second. I know I have	3	daily for one year, one to five years, five to 20
4	cited them, and I'm just trying to find where.	4	years, and more than 20 years. Is that right?
5	Yeah. None of the cohort studies were able	5	A. Yes.
6	to conduct meaningful dose-response because they	6	Q. There was only statistical significance
7	did not collect durational.	7	for the time periods of one to five years of use
8	Q. Are those the only studies, the cohort	8	and more than 20 years of use; correct?
9	studies that did not find a meaningful	9	A. Yes.
10	dose-response?	10	Q. If there is a dose-response, shouldn't
11	A. No. There were several	11	there continue to be statistical significance
12	MS. PARFITT: Objection to form.	12	with increased exposure?
13	A. There were other case-control studies.	13	MS. PARFITT: Objection. Form.
14	No. If you take out 41, 55 I mean, these	14	A. Yeah. So that is I'm just
15	references cite above that are, you know,	15	concluding what they concluded. The trend for
16	included in the sections, and I talk about their	16	frequency of use was significant, but the trend
17	dose-response in the respective section.	17	for use years use was flat. And if you look
18	Q. What is your justification for	18	at Page 337, the last line of that paragraph,
19	disregarding the studies that did not show a	19	"Even with this imprecision, the trend remained,
20	dose-response?	20	although the increase was less monotonic."
21	MS. PARFITT: Objection. Form.	21	Q. When we look at the data, there is only
22	A. So I did not disregard these studies.	22	a dose-response strike that.
23	They are included in the report. So, obviously,	23	The data only shows statistical significance
24	the cohort studies already are, and we can go	24	for one to five years of use. It does not show
25	through the case-control studies, which did not	25	statistical significance for one year or five to
	Page 179		Page 181
1	show dose-response and are included.	1	20 years; correct?
2	Q. One of the studies you reviewed and	2	MS. PARFITT: Objection. Misstates the
3	considered and relied upon was the Cramer 2016	3	evidence.
4	study; is that right?	4	A. Yeah. So let's go to
5	A. Yeah.	5	Q. Is that correct?
6	(Article entitled "The	6	MS. PARFITT: Objection.
7	Association Between Talc Use and Ovarian	7	A. Yes. But let's go to the section of my
8	Cancer, A Retrospective Case-Control Study	8	testimony in which report which discusses how
9	in Two US States" marked Exhibit 24.)	9	dose-response analysis should be interpreted,
10	BY MR. ZELLERS:	10	because they lose statistical power. So subgroup
11	Q. Exhibit 24 is the Cramer 2016 study;	11	tests lose statistical significance, and I'll
12	correct?	12	point out
13	A. Yes.	13	Q. You
14	Q. This is a retrospective case-control	14	MS. PARFITT: Excuse me. I think he's
15	study published in 2016; is that right?	15	still
16	A. Yes.	16	A. Yeah. I'm trying to explain something.
17	Q. You claim in your report that this	17	Yeah. We are talking on the subject of
18	study shows a trend for increasing risk by talc	18	dose-response. And one must be careful in
19	years on Page 46, the last paragraph; is that	19	interpreting data from the subgroup analysis such
20	right?	20	as analysis of dose categories or, you know, as
21	A. Yes.	21	subgroups. The results are important. If the
22	Q. Let's take a look at whatever the study	22	test is not significant, there's lack of
23	shows. Turn to Page 337 of Exhibit 24, the	23 24	significant difference. However, such subgroup
24 25	Cramer 2016 study. A. 337? Yes.	25	tests can be underpowered because of reduction in sample size.
		. 43	SHILDIC SIZE.

46 (Pages 178 to 181)

	Page 184
1 Q. Doctor, if there is a dose-response in 1 that testing to determine	how much talcum powder
2 a study such as the Cramer 2016 paper, looking at 2 reaches a woman's ovary	-
	idea how much asbestos
4 statistical significance with increased exposure? 4 reaches a woman's ovari	ies each time she uses
5 MS. PARFITT: Objection. 5 talc, assuming that talc p	bowder is contaminated
6 A. No, no, you don't it doesn't have to 6 with asbestos?	
7 be statistical significance with, you know, 7 MS. PARFITT: C	Objection. Form.
8 increased exposure. I mean, you look at the test 8 A. I have not condu	cted that assessment.
9 score interaction. 9 Q. How much heavy	y metal exposure reaches a
So I don't think that, with each category of 10 woman's ovaries, assum	ing that there are heavy
exposure, you're already you have a power for 11 metals in talcum powder	r?
12 a study. Now with each, you're decreasing the 12 MS. PARFITT: C	Objection. Form.
number of users, so you're not going to get 13 A. I have not condu	cted that assessment.
14 statistical significance. 14 Q. Do you know that	at heavy metals,
15 Q. Then why do you get statistical 15 chromium, cobalt and ni	ickel, are in vitamins?
significance at greater than 20 years of daily  16  A. Yeah. They are	
17 use? 17 are ubiquitous in various	s other areas as well.
A. Yeah. Because there's differential, 18 Q. They're in food;	~
you know at that point, you know, there's 19 A. I don't know whi	
20 more there's, you know, more case subjects 20 Yeah. I can't be specific	
21 have ovarian cancer. 21 Q. In drinking water	
Q. Why do you not have statistical 22 A. I don't know. I do	lon't want to say yes
23 significance at five to 20 years? 23 to whichever.	
A. Because it's underpowered at that time. 24 Q. It's in bottled wa	
25 Q. Why do you not have statistical 25 A. I don't know that	i.
Page 183	Page 185
	Page 185
	s, chromium, cobalt and
1 significance at one year? 1 Q. Are heavy metal	s, chromium, cobalt and
1 significance at one year? 1 Q. Are heavy metal 2 A. It's underpowered. 2 nickel, considered essen	s, chromium, cobalt and tial nutrients in the
significance at one year?  A. It's underpowered.  Q. Are heavy metal nickel, considered essent body?  Unickel, considered essent body?	is, chromium, cobalt and atial nutrients in the Objection. hat's, you know,
significance at one year?  A. It's underpowered.  Q. But it is appropriately powered at one to five years?  A. Yes. Based on the number of cases. Q. Isn't this an instance where you're  1 Q. Are heavy metal nickel, considered essent body?  4 body?  4 MS. PARFITT: 0  A. Yeah. I mean, the constant of this or it's pertaining to this o	is, chromium, cobalt and atial nutrients in the Objection. hat's, you know, case, the question is
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	Page 186		Page 188
1		1	
1	you repeat?	1	infer from whatever the biological evidence that
2 3	<ul><li>Q. Sure. I'll ask it again.</li><li>You have no evidence that the blood or</li></ul>	2 3	I've reviewed, that there's, you know, evidence
3 4	tissue levels of any trace heavy metals are		that supports biologic probability. There are some studies that, you know, don't support that
5		4 5	claim.
6	higher in genital talc users compared to nonusers; correct?	6	Q. My question simply was if you defer to
7	MS. PARFITT: Objection. Form.	7	other experts on the topic of biologic
8	A. Yeah. But I do know that there is	8	plausibility.
9	perineal talc application, and at least from the	9	MS. PARFITT: Objection.
10	documents I have reviewed, that, you know,	10	Q. You do; correct?
11	asbestos is present in tale, at least from the	11	MS. PARFITT: Objection. That's not
12	documents I've reviewed, from the studies that	12	his testimony.
13	I've reviewed, and from a as you say, the	13	A. I won't just defer to them. I'm just
14	excerpts of the deposition.	14	providing my own opinion. Yeah. I mean, they
15	And, you know, whether these are in blood	15	can provide you know, it depends. If it's a
16	levels or, as you said, in the uterine tissue,	16	plaintiff expert, a defense expert. I mean, how
17	no, I don't know that.	17	do I know? I can't defer to somebody without
18	Q. Another Bradford Hill overview factor	18	reading their opinion; right?
19	is biological plausibility; right?	19	Q. Is all ovarian cancer caused by the
20	A. Well, it's actually plausibility.	20	same mechanism?
21	Q. Plausibility means that a biological	21	A. No. And neither is any kind of cancer.
22	mechanism exists; correct?	22	Q. Different subtypes of cancer have
23	A. Well, that's what we mean. But if you	23	different biological mechanisms; correct?
24	actually go back and read Bradford Hill, he was	24	A. Yes. But we are dealing with biologic
25	talking even about social factors. Yes, but, you	25	plausibility.
23	taiking even about social factors. Tes, but, you	23	plausionity.
	Page 187		- 100
	rage 107		Page 189
1	know, we've gone forward and interpreted that as	1	Page 189  Again, I don't need to know the precise
1 2		1 2	
	know, we've gone forward and interpreted that as		Again, I don't need to know the precise
2	know, we've gone forward and interpreted that as biologic plausibility.	2	Again, I don't need to know the precise biological mechanisms to arrive at a causal
2	know, we've gone forward and interpreted that as biologic plausibility.  Q. The biological mechanisms of cancer are	2	Again, I don't need to know the precise biological mechanisms to arrive at a causal opinion.
2 3 4	know, we've gone forward and interpreted that as biologic plausibility.  Q. The biological mechanisms of cancer are not your area of expertise; is that right?	2 3 4	Again, I don't need to know the precise biological mechanisms to arrive at a causal opinion.  Q. If talc is associated with all subtypes
2 3 4 5	know, we've gone forward and interpreted that as biologic plausibility.  Q. The biological mechanisms of cancer are not your area of expertise; is that right?  MS. PARFITT: Objection.	2 3 4 5	Again, I don't need to know the precise biological mechanisms to arrive at a causal opinion.  Q. If talc is associated with all subtypes of epithelial ovarian cancer, or with different
2 3 4 5 6	know, we've gone forward and interpreted that as biologic plausibility.  Q. The biological mechanisms of cancer are not your area of expertise; is that right?  MS. PARFITT: Objection.  A. Yes. But, again, the question for me	2 3 4 5 6	Again, I don't need to know the precise biological mechanisms to arrive at a causal opinion.  Q. If talc is associated with all subtypes of epithelial ovarian cancer, or with different subtypes in different studies, doesn't that
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	Page 190		Page 192
1	migrates upwards and upwards through the, you	1	A. Yeah. I know that.
2	know, vaginal canal and migrates to.	2	Q. Ness is an expert for plaintiffs in the
3	Q. Is that an area of your expertise?	3	talc litigation; is that right?
4	A. Again, no. But I have reviewed the	4	MS. PARFITT: Objection.
5	studies, several studies that some studies	5	A. I'm not aware of that.
6	that I cite, several studies that were added.	6	Q. So Justin, that dealt with glove
7	And it's quite well accepted, at least in the	7	powder; is that right?
8	gynecological community, that there's, you know,	8	A. Which one was that, 68?
9	particulate matter can migrate upwards.	9	Q. 68.
10	Q. What studies support the theory that	10	A. Yes.
11	talcum powder applied externally migrates from	11	Q. Isn't it true that that study did not
12	the perineal region to the ovaries?	12	involve perineal use, but an exam with force to
13	A. Again, I reviewed various studies on	13	the cervix?
14	migration.	14	A. Yeah. You know, and I'm relying on it,
15	Q. Can you name them for me?	15	again, for biologic plausibility. It does not
16	A. I'm going to look at it.	16	involve talc. So, you know, it's glove powder
17	Yeah. So I cite several studies in this	17	in
18	section on migration. And, again, this in the	18	Q. Isn't it true that they found some
19	context of biologic plausibility. Is it	19	particles in women who were examined with
20	plausible that particulate matter, such as talc,	20	powder-free gloves?
21	can migrate? And, again	21	A. Yes.
22	Q. What page are you looking at?	22	Q. Heller, didn't Heller find talc in
23	A. Sorry. 57.	23	tissues in all 24 patients, including the 12 who
24	Q. What studies are you relying on?	24	did not use perineal talc?
25	A. Yeah. So I'm relying on the studies	25	A. Yes.
	Page 191		Page 193
1	described by, you know, Heller, 64.	4	Q. What is the evidence in the ovarian
		1	Q. What is the evidence in the ovarian
2		2	•
2 3	Q. Any others? A. 65.		tissues that have been studied of granulomatous
	Q. Any others?	2	•
3	<ul><li>Q. Any others?</li><li>A. 65.</li></ul>	2	tissues that have been studied of granulomatous reaction which is what you would see if there was
3 4	<ul><li>Q. Any others?</li><li>A. 65.</li><li>Q. What is 65?</li></ul>	2 3 4	tissues that have been studied of granulomatous reaction which is what you would see if there was a huge amount of talc?
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49 (Pages 190 to 193)

	Page 194		Page 196
1	MS. PARFITT: Objection. Form.	1	history of breast cancer, had a tubal ligation or
2	A. I did not review those studies, if	2	hysterectomy, were pre-menopausal or were
3	there are.	3	post-menopausal and used HT."
4	Q. In your report, you say that, "The	4	Is that correct?
5	migration theory is supported by findings of a	5	A. Yeah.
6	deceased risk" strike that.	6	Q. So, in fact, Cramer did find a
7	In your report, you say that, "The migration	7	significantly greater association between talcum
8	theory is supported by findings of a decreased	8	powder use and ovarian cancer for women who had a
9	risk of ovarian cancer with tubal ligation and	9	tubal ligation; is that right?
10	hysterectomy." Pages 18 and 19.	10	A. Yeah. But my my point, in Page 57,
11	Is that right?	11	is that, you know, first of all, that's more than
12	A. Yes.	12	just one Cramer. There are several studies that
13	Q. Don't the studies pertaining to tubal	13	in inferring biologic plausibility, tubal
14	ligation show mixed results?	14	ligation and hysterectomy are protective of
15	A. No.	15	ovarian cancer. It is not that talc in this had
16	MS. PARFITT: Objection.	16	a higher risk among those.
17	A. As far as	17	I mean, those, again, those are not two
18	MS. PARFITT: Sorry.	18	incongruent arguments. I mean, Cramer is making
19	A. I mean, as far as I'm aware, you know,	19	a separate argument that, in his study, he found
20	tubal ligation and hysterectomy are protective	20	a higher risk among those who had tubal ligation
21	risk factors for ovarian cancer.	21	or hysterectomy.
22	Q. That's your opinion based upon your	22	Q. If you're correct in the opinion that
23	review and analysis of the literature; is that	23	you set forth in your report, you would have
24	right?	24	expected the Cramer study to show a decreased
25	A. Yeah.	25	risk of ovarian cancer for women who had tubal
	71. Tour.	23	risk of ovarian cancer for women who had tubar
		1	
	Page 195		Page 197
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1 2		1 2	Page 197 ligation or hysterectomy; correct? MS. PARFITT: Objection. Form.
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	Page 198		Page 200
1	appendix, because that actually breaks it down by	1	talc users who had a tubal ligation; correct?
2	tubal ligation and hysterectomy.	2	A. I mean, I think I need to look at the
3	You're asking very specific questions. I	3	data. I think I don't have it. We are trying
4	need to have specific materials.	4	to get it, so we'll have to wait.
5	MR. TISI: I have them.	5	I mean, you're asking me questions. I mean,
6	Q. What are you asking for?	6	you have to show me documents. I mean
7	A. You asked a question about tubal	7	Q. Well, you made a statement in your
8	ligation.	8	report
9	Q. I understand. What are you asking	9	A. How can I make a statement in the
10	counsel for plaintiffs to get you?	10	report around Taher, because it wasn't even
11	A. The Taher appendix.	11	available at that time?
12	Q. You want to go back and look at the	12	Q. What I'm trying to do is ask you
13	Taher	13	A. Sure.
14	A. Appendix. Because they did stratify	14	Q about the statement in your report,
15	the analysis by hysterectomy and tubal ligation.	15	where you say that, "Migration theory is
16	Q. That's the 2018, unpublished paper; is	16	supported by findings of a decreased risk of
17	that right?	17	ovarian cancer with tubal ligation and
18	A. Yes.	18	hysterectomy."
19	Q. All right. Did the Houghton as	19	A. And I'm just stating that I just need
20	they're looking for this	20	to look at a figure in the Taher appendix and
21	A. Yeah. Sure.	21	then I'll be able to answer that. That's all.
22	Q. Did the Houghton two thousand strike	22	Q. Well, we saw that Cramer doesn't show
23	that.	23	that; right?
24	The Houghton 2014 study also did not show a	24	A. Yes.
25	reduction of ovarian cancer in talc users who	25	Q. You're not aware that Gertig 2000 or
	Page 199		Page 201
1	have had tubal ligation; correct?	1	Houghton 2014 shows that. Are you?
2	A. Again, you know, I don't want to agree	2	MS. PARFITT: Objection. Misstates his
3	or disagree with you without just looking at it.	3	testimony.
4	I don't think I comment on it.	4	A. You have not shown me that. You have
5	Q. Would you agree or can you agree that	5	not shown me documents to say one way or the
6	both Gertig 2000 and Houghton 2014 were large	6	other.
7	prospective cohort studies; right?	7	Q. When you did your analysis, didn't you
8	A. Yeah. But we've already discussed	8	look at the studies to try to see if they
9	their limitation in terms of they were not	9	supported or refuted the points you were making?
10	designed to study the talc ovarian cancer. They	10	A. I you know, I did not look at every
11	had prevalent user biases. You know, they lost a	11	subanalysis by, you know by whether it's, you
12	lot of users and cases of ovarian cancer. You	12	know, pre-menopausal, post-menopausal.
13	know, they had misclassification.	13	Q. You cite Cramer 2016 as supportive of
14	And, yes, they were large studies, but had	14	your position and opinions.
15	small number of ovarian cancer cases.	15	A. Sure.
16	MR. KLATT: Objection. Nonresponsive.	16	Q. Is that right?
	MR. ZELLERS: Join.	17	A. Well, again
17		18	MS. PARFITT: Objection. Mis
	Q. You read the Ter Riet 2013		
17		19	A. I don't.
17 18	Q. You read the Ter Riet 2013	19 20	A. I don't.  MS. PARFITT: Let me get my objection
17 18 19 20 21	<ul><li>Q. You read the Ter Riet 2013</li><li>meta-analysis; is that right?</li><li>A. Yes.</li><li>Q. You rely on that; correct?</li></ul>	19 20 21	MS. PARFITT: Let me get my objection in.
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17 18 19 20 21 22 23	<ul> <li>Q. You read the Ter Riet 2013</li> <li>meta-analysis; is that right?</li> <li>A. Yes.</li> <li>Q. You rely on that; correct?</li> <li>A. Yes.</li> <li>MS. PARFITT: Objection.</li> </ul>	19 20 21 22 23	MS. PARFITT: Let me get my objection in.  THE WITNESS: Sorry. Go ahead.  MS. PARFITT: No. My objection is in,

51 (Pages 198 to 201)

	Page 202		Page 204
1	parts of Cramer 2016, Gertig 2000, Houghton 2014,	1	by findings of a decreased risk of ovarian cancer
2	Ter Riet 2013, Rosenblatt 2011, Wong 1999, Cook	2	with tubal ligation and hysterectomy.
3	1997, Harlow 1992, that don't support your	3	A. Yeah. But it doesn't talk about, you
4	position.	4	know so if you look at the reference, in
5	MS. PARFITT: Counsel completely	5	case-control studies and meta-analysis, let's
6	misstates his opinion. The question misstates	6	look at the references. You know, so, yes,
7	A. I don't even know what was the	7	there's one. And if let's look at
8	question, and I can't answer that because I don't	8	Q. Okay. Can you cite one reference?
9	know what the question was.	9	A. Yeah. Let's look at that.
10	Q. The question is: When you opined in	10	Q. All right.
11	your report that the migration theory is	11	A. Then let's look at 115. So when I cite
12	supported by findings of a decreased risk of	12	115, that's not even about talc. That's about
13	ovarian cancer with tubal ligation and	13	tubal ligation and hysterectomy, in general, is
14	hysterectomy, did you pick out just a couple of	14	it you know, so taking tale out of the
15	cases to look at and cite or did you try to see	15	equation, I'm trying to opine or understand
16	if there was consistency to that finding across	16	whether tubal ligation and hysterectomy are
17	all of the studies?	17	protective factors, and then I can infer on talc,
18	A. Yeah. So when I cite that, and you can	18	yes, should only Ness have been cited? Yes,
19	see the citation, I am trying to make an	19	there are other studies otherwise.
20	inference about separate from talc use, and	20	Q. And there are other studies, many
21	ovarian cancer, you know, is hysterectomy and	21	studies
22	tubal ligation protective of that.	22	A. Yes.
23	So that's the inference. It's not that each	23	Q that do not support your position;
24	of these studies, I'm trying to ignore, you know,	24	is that right?
25	the studies that you mentioned. I'm just trying	25	MS. PARFITT: Objection. Form. His
	Page 203		Page 205
1	to say, as you're looking at mechanisms, what	1	position on tubal ligation?
2	would happen with tubal I'm trying to do the	2	MR. ZELLERS: Yes.
3	best to explain, tubal ligation and ovarian	l _	MS. PARFITT: Thank you.
4		3	MS. PARFILL: Hank you.
-	cancer.	4	A. Yeah. So it's it's I think
5			<del>-</del>
	cancer.	4	A. Yeah. So it's it's I think
5	cancer.  If, in the individual studies, yes, as in	4 5	A. Yeah. So it's it's I think there's I mean, whether Ness and others should
5 6	cancer.  If, in the individual studies, yes, as in  Cramer, and if we see that in the other studies,	4 5 6	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But
5 6 7	cancer.  If, in the individual studies, yes, as in  Cramer, and if we see that in the other studies, then, you know, they provide a different opinion.	4 5 6 7	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and
5 6 7 8	cancer.  If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the	4 5 6 7 8	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you
5 6 7 8 9	cancer.  If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the general knowledge of tubal ligation and	4 5 6 7 8 9	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you know, migration hypothesis.
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5 6 7 8 9 10 11	cancer.  If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the general knowledge of tubal ligation and hysterectomy being, you know, protective.  Q. Do you agree with me, to have a scientifically valid opinion	4 5 6 7 8 9 10 11	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you know, migration hypothesis.  BY MR. ZELLERS:  Q. You should at least cite to or make some reference A. Yeah. Q right, to the studies that do not
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5 6 7 8 9 10 11 12 13 14 15	cancer.  If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the general knowledge of tubal ligation and hysterectomy being, you know, protective.  Q. Do you agree with me, to have a scientifically valid opinion A. Sure. Q you need to look at all of or at least the important studies; correct? A. Yeah. I did look at these studies.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you know, migration hypothesis.  BY MR. ZELLERS:  Q. You should at least cite to or make some reference  A. Yeah.  Q right, to the studies that do not support that position?  A. Yeah. And I think that I have made it in the individual sections, and I can try to look for it, but it will take us time there.
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5 6 7 8 9 10 11 12 13 14 15 16 17 18	cancer.  If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the general knowledge of tubal ligation and hysterectomy being, you know, protective.  Q. Do you agree with me, to have a scientifically valid opinion  A. Sure.  Q you need to look at all of or at least the important studies; correct?  A. Yeah. I did look at these studies.  Q. And, in fact, a number of the studies that you cite in your report  A. Sure.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you know, migration hypothesis.  BY MR. ZELLERS:  Q. You should at least cite to or make some reference  A. Yeah.  Q right, to the studies that do not support that position?  A. Yeah. And I think that I have made it in the individual sections, and I can try to look for it, but it will take us time there.  Q. Isn't there evidence that if tubal ligation has a protective effect, the protective effect in ovarian cancer stems from the fact that
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	cancer.  If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the general knowledge of tubal ligation and hysterectomy being, you know, protective.  Q. Do you agree with me, to have a scientifically valid opinion  A. Sure.  Q you need to look at all of or at least the important studies; correct?  A. Yeah. I did look at these studies.  Q. And, in fact, a number of the studies that you cite in your report  A. Sure.  Q don't support your position; correct?  MS. PARFITT: Objection. Form.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you know, migration hypothesis.  BY MR. ZELLERS:  Q. You should at least cite to or make some reference  A. Yeah.  Q right, to the studies that do not support that position?  A. Yeah. And I think that I have made it in the individual sections, and I can try to look for it, but it will take us time there.  Q. Isn't there evidence that if tubal ligation has a protective effect, the protective effect in ovarian cancer stems from the fact that the ligation procedure itself changes the
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	cancer.  If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the general knowledge of tubal ligation and hysterectomy being, you know, protective.  Q. Do you agree with me, to have a scientifically valid opinion  A. Sure.  Q you need to look at all of or at least the important studies; correct?  A. Yeah. I did look at these studies.  Q. And, in fact, a number of the studies that you cite in your report  A. Sure.  Q don't support your position; correct?  MS. PARFITT: Objection. Form. Support his position on tubal ligation?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you know, migration hypothesis.  BY MR. ZELLERS:  Q. You should at least cite to or make some reference  A. Yeah.  Q right, to the studies that do not support that position?  A. Yeah. And I think that I have made it in the individual sections, and I can try to look for it, but it will take us time there.  Q. Isn't there evidence that if tubal ligation has a protective effect, the protective effect in ovarian cancer stems from the fact that
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	cancer.  If, in the individual studies, yes, as in Cramer, and if we see that in the other studies, then, you know, they provide a different opinion. But I'm trying to make an opinion, based on the general knowledge of tubal ligation and hysterectomy being, you know, protective.  Q. Do you agree with me, to have a scientifically valid opinion  A. Sure.  Q you need to look at all of or at least the important studies; correct?  A. Yeah. I did look at these studies.  Q. And, in fact, a number of the studies that you cite in your report  A. Sure.  Q don't support your position; correct?  MS. PARFITT: Objection. Form.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yeah. So it's it's I think there's I mean, whether Ness and others should have been cited there, that's a valid point. But when I make a point about tubal ligation and hysterectomy, it's a general point on the, you know, migration hypothesis.  BY MR. ZELLERS:  Q. You should at least cite to or make some reference  A. Yeah.  Q right, to the studies that do not support that position?  A. Yeah. And I think that I have made it in the individual sections, and I can try to look for it, but it will take us time there.  Q. Isn't there evidence that if tubal ligation has a protective effect, the protective effect in ovarian cancer stems from the fact that the ligation procedure itself changes the

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	Page 206		Page 208
1	A in, you know, this area to provide,	1	concentration in the rectal, vulvar, vaginal,
2	you know, why it would do that.	2	cervical, and uterine tissues which are closer to
3	Q. Did you review or are you familiar with	3	the area of the initial exposure; correct?
4	Tiourin, T-I-O-U-R-I-N, a 2015 study?	4	MS. PARFITT: Objection. Misstates his
5	A. Did I cite that? I don't remember.	5	testimony.
6	Q. Are you is that study familiar to	6	A. I just don't have an opinion in terms
7	you?	7	of where it will be high or low. Because that's
8	A. I just can't remember the names. There	8	not my area of expertise.
9	are so many studies. If you show it to me, I	9	Q. Talc particles should be causing
10	can	10	inflammation in all those organs and areas;
11	Q. I'll show it to you. You can tell me	11	correct?
12	if it's familiar to you. And if it's not, I'll	12	MS. PARFITT: Objection.
13	move on.	13	A. Again, that's that's, you know, I'm
14	(Article entitled "Tubal	14	opining on biological plausible mechanisms of
15	Ligation Induces Quiescence in the	15	talc-induced ovarian cancer. I didn't look at,
16	Epithelia of the Fallopian Tube Fimbria"	16	you know, whether it's vaginitis or vulvar or
17	marked Exhibit 25.)	17	whether it's, you know, rectal inflammation. And
18	MR. ZELLERS: 25 is the	18	that's not my area of expertise again.
19	A. No, it's not. I don't know about.	19	Q. In fact, there are no studies that show
20	BY MR. ZELLERS:	20	inflammation as a result of genital talc use in
21	Q. For the record, 25 is a 2015 study by	21	any of those areas; correct?
22	Tiourin, T-I-O-U-R-I-N.	22	MS. PARFITT: Objection. Misstates the
23	That's not a study that you reviewed or	23	evidence.
24	considered; is that right?	24	A. Again, I have not you know, my
25	A. You know, I have to go through all the	25	testimony and report on talcum powder products
	Page 207		Page 209
1	references, but I can't recall straight off	1	and inflammation is looking at, are there
2	whether it does.	2	biological plausible mechanisms.
3	Q. If talcum powder migrates from the	3	And, again, if there's no studies that
4	perineal region to the ovaries, shouldn't	4	provide that talc, in and of itself, causes
5	exposure to talc be far greater in concentration	5	inflammation, then there are no studies. But,
6	in the rectal, vulvar, vaginal, cervical and	6	you know, but there's still biologic
7	uterine tissues?	7	plausibility.
8	MS. PARFITT: Objection to form.	8	•
	<i>3</i>	0	MR. KLATT: Objection. Unresponsive.
9	Q. Because those are closer to the area of	9	MR. KLATT: Objection. Unresponsive. Q. Are there any studies that you are
9 10			Q. Are there any studies that you are
	initial exposure?	9	Q. Are there any studies that you are aware that show a link between external genital
10	initial exposure?  MS. PARFITT: Same objection.	9 10	Q. Are there any studies that you are
10 11	initial exposure?	9 10 11	Q. Are there any studies that you are aware that show a link between external genital talc use and rectal, vulvar, vaginal, cervical,
10 11 12	initial exposure?  MS. PARFITT: Same objection.  A. Yes. So, again, my I did not examine, you know, which areas of now, as an	9 10 11 12	Q. Are there any studies that you are aware that show a link between external genital talc use and rectal, vulvar, vaginal, cervical, or uterine cancer?  MS. PARFITT: Asked and answered.
10 11 12 13	initial exposure?  MS. PARFITT: Same objection.  A. Yes. So, again, my I did not examine, you know, which areas of now, as an epidemiologist, I examine general exposures to,	9 10 11 12 13	Q. Are there any studies that you are aware that show a link between external genital talc use and rectal, vulvar, vaginal, cervical, or uterine cancer?
10 11 12 13 14	initial exposure?  MS. PARFITT: Same objection.  A. Yes. So, again, my I did not examine, you know, which areas of now, as an epidemiologist, I examine general exposures to, you know, products and their associations.	9 10 11 12 13 14	Q. Are there any studies that you are aware that show a link between external genital talc use and rectal, vulvar, vaginal, cervical, or uterine cancer?  MS. PARFITT: Asked and answered. Objection.
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10 11 12 13 14 15 16 17 18 19 20	initial exposure?  MS. PARFITT: Same objection.  A. Yes. So, again, my I did not examine, you know, which areas of now, as an epidemiologist, I examine general exposures to, you know, products and their associations.  Whether, you know, we want to know, yes, route of exposure, whether it's perineal application.  But, you know, the evidence that I examined was, you know, I did not distinguish within whether it was perineal or vaginal, vulvar. That would have been different.	9 10 11 12 13 14 15 16 17 18 19 20	Q. Are there any studies that you are aware that show a link between external genital talc use and rectal, vulvar, vaginal, cervical, or uterine cancer?  MS. PARFITT: Asked and answered. Objection.  A. I'm not aware of those. I have not reviewed those studies.  Q. As part of your report, you discuss a study published by Huncharik and others in 2007; is that right?  A. Yes. Let's bring it out, I mean, if you want to talk about that.
10 11 12 13 14 15 16 17 18 19 20 21	initial exposure?  MS. PARFITT: Same objection.  A. Yes. So, again, my I did not examine, you know, which areas of now, as an epidemiologist, I examine general exposures to, you know, products and their associations.  Whether, you know, we want to know, yes, route of exposure, whether it's perineal application.  But, you know, I did not distinguish within whether it was perineal or vaginal, vulvar. That would have been different.  Q. Let's go step by step.	9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Are there any studies that you are aware that show a link between external genital talc use and rectal, vulvar, vaginal, cervical, or uterine cancer?  MS. PARFITT: Asked and answered. Objection.  A. I'm not aware of those. I have not reviewed those studies.  Q. As part of your report, you discuss a study published by Huncharik and others in 2007; is that right?  A. Yes. Let's bring it out, I mean, if you want to talk about that.  Q. I believe it's on Page 26 of your
10 11 12 13 14 15 16 17 18 19 20 21 22	initial exposure?  MS. PARFITT: Same objection.  A. Yes. So, again, my I did not examine, you know, which areas of now, as an epidemiologist, I examine general exposures to, you know, products and their associations.  Whether, you know, we want to know, yes, route of exposure, whether it's perineal application.  But, you know, the evidence that I examined was, you know, I did not distinguish within whether it was perineal or vaginal, vulvar. That would have been different.	9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Are there any studies that you are aware that show a link between external genital talc use and rectal, vulvar, vaginal, cervical, or uterine cancer?  MS. PARFITT: Asked and answered. Objection.  A. I'm not aware of those. I have not reviewed those studies.  Q. As part of your report, you discuss a study published by Huncharik and others in 2007; is that right?  A. Yes. Let's bring it out, I mean, if you want to talk about that.

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#### Page 210 Page 212 1 studies on the relationship between ovarian 1 means that you cannot exclusively focus on one 2 2 cancer and using diaphragms that are dusted with route of exposure. So it does not mean that it 3 3 talcum powder; is that right? cannot in and of itself. You have to look at 4 4 A. Yes. perineal-dusted diaphragm. You have to look at, 5 5 Q. A diaphragm is inserted directly onto a other, you know, perineal applications. 6 woman's cervix; is that right? 6 Q. So putting aside inhalation for the 7 A. Yes. 7 moment, your opinion is that talcum powder 8 Q. On Page 26 of your report, you say 8 travels from the perineal region to the ovaries 9 9 that, "This meta-analysis is flawed because it through the woman's reproductive tract; is that 10 only focuses on powder-dusted diaphragms"; 10 right? 11 11 correct? A. I mean, I don't even know through the 12 A. Well, no. That's not the only flaw. I 12 ovaries. I know it migrates upwards. That's, 13 mean, there are several other flaws, including 13 you know, my opinion. 14 14 Q. So talcum powder must travel past the exclusion of loss category, data extraction 15 15 analysis, which is, you know, really inclusion of labia, through the vagina, through the cervix, 16 inability studies that did not disaggregate. 16 and then to the uterus; is that right? 17 17 I mean, the question is if you're asking A. Yes. It migrates upwards through the 18 about perineal exposure, yes, perineal --18 vagina, you know, the tract. 19 diaphragms is one route of exposure. But that's 19 Q. And then the powder travels through the 20 20 not the only route of exposure that you should be uterus and into the fallopian tubes to reach the 21 concerned about. 21 ovaries; is that right? 22 22 Q. Do you state in your report, "The most A. Well, I mean, I'm not -- again, I don't 23 important limitation with the Huncharik 2007 23 intend to elucidate, you know, the precise link 24 meta-analysis was its exclusive focus on talc 24 that a study has shown that talcum powder -- I 25 powder-dusted diaphragms as the route of 25 think we answered this earlier, I answered this Page 211 Page 213 1 1 exposure, which could not inherently address the earlier -- that I am not aware of one study that 2 2 causal question of whether genital talcum powder shows that. But, you know, several shows that 3 3 dusting is associated with increased risk of talc ends up in the ovaries. 4 ovarian cancer"? 4 Q. Well, given how talc, talcum powder 5 5 Is that what you said? must travel to reach the ovaries, how can you 6 6 MS. PARFITT: Counsel, do you have a exclude data about the relationship between 7 7 copy of the -- otherwise, may I show him the ovarian cancer and talcum powder that is applied 8 Huncharik study so he's got it in front of him? 8 directly to the cervix? 9 9 MR. ZELLERS: I'm just asking general MS. PARFITT: Objection. Misstates his 10 10 questions right now. That was just a question, testimony. 11 does he say that in his report. If he needs to 11 A. Nobody is excluding data. So this is 12 review the study, then he can look at the study. 12 not exclusion of this data. 13 13 MS. PARFITT: I would appreciate that. But I am saying that this particular 14 MR. ZELLERS: Sure. 14 question of talc-dusted diaphragms, A, is an 15 MS. PARFITT: I just didn't want to 15 exclusive focus on one route of exposure, so it 16 pass something to him without your permission. 16 does not answer the causal question about 17 A. Yeah. I do state that. 17 perineal exposure. 18 Q. You say that, "Studies on the use of 18 And, two, it is not excluded. It's included 19 19 talcum powder-dusted diaphragms cannot address and discussed and several flaws are noted, 20 the question of whether perineal use is 20 including, you know, data extraction errors for 21 associated with an increased risk of ovarian 21 the most part, inclusion of studies. 22 cancer"; correct? 22 And so -- and as can you see in my 23 23 methodological rating of meta-analyses, it is A. Where is that? 24 24 weighted differently than others. So it is not Q. It's what we just read. 25 A. No. It doesn't mean that. It just 25 excluded.

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#### Page 214 Page 216 Q. But you state, as the most important 1 1 don't know anything about. I don't -- you know, 2 limitation of the Huncharik 2007 study, is the 2 I haven't reviewed it to answer that question. 3 exclusive focus on talc powder-dusted diaphragms. 3 Q. Do you have an opinion on whether 4 A. Yeah. 4 inhaled talc can migrate to the ovaries? 5 5 Q. And those diaphragms are applied A. Yeah. I mean, I think the primary 6 6 directly to the cervix; is that right? route of exposure is, you know, reproductive, but 7 7 A. Yeah. Because -- because of its there are some potential, I would say, you know, 8 8 exclusive focus. If the study had, you know, potential plausible mechanisms that, you know, 9 9 other routes of exposure, yeah. when perineal application is applied, it can get 10 What I'm trying to say is its exclusive 10 inhaled through the lungs and potentially reach 11 focus on one route of exposure cannot -- if 11 the ovaries. But I think that that mechanism is 12 12 you're just asking the question about dust, probably not as plausible as the reproductive 13 dusted diaphragm, then don't make inferences 13 mechanism. 14 about perineal routes of exposure. You have to 14 Q. Well, in fact, studies of talcum powder 15 look at broader exposures. 15 use failed to show a statistically significant association between nongenital use of talcum 16 Q. On what studies are you relying to say 16 17 that talcum powder affects the body differently 17 powder and ovarian cancer; correct? 18 when it is applied to the perineal region and MS. PARFITT: Objection. Form. 18 travels to the cervix compared to when it is A. Yeah. And I've cited those studies. 19 19 applied directly to the cervix? 20 20 Q. If inhaled talc could migrate to the A. I have not made a distinction between ovaries, wouldn't you expect to see increased 21 21 22 ovarian cancer risk with nongenital use of talcum those studies. 22 23 Q. And, in fact, when applied to the 23 powder? perineal region, the talcum powder would also be 24 24 MS. PARFITT: Objection. 25 in close contact with a woman's urethra; is that 25 A. Well, I mean, it also depends on, you Page 215 Page 217 1 1 know, the quantity of inhalation, the degree of right? 2 MS. PARFITT: Objection. Form. 2 talc that's -- and I don't know enough about that 3 A. Yeah. I mean, anatomically. 3 to say that, yes, there's a sufficient quantity, Q. Substances are capable of traveling up you know, migration to cause that. I don't know 4 4 5 5 which studies have evaluated sort of inhaled talc the urethra; correct? A. I mean, yes. Just as we agree that, 6 6 and ovarian cancer. 7 you know, talc can migrate upwards, substances 7 Q. Well, let's look back at Cramer 2016, can migrate through the urethra. If you agree 8 8 Page -- or Exhibit 24. Do you have that in front 9 talc can migrate upwards, then, you know, 9 of you? 10 substances can migrate through the urethra. 10 A. Yeah. Q. Women get urinary tract infections when 11 11 Q. In that study, Cramer found no apparent bacteria travels up the urethra; correct? risk associated with nongenital talc use; isn't 12 12 A. Yeah. 13 13 that correct? 14 O. But studies do not show an increase in 14 A. Yeah. And I think I cite that in my 15 bladder cancer with talcum powder use, do they? 15 report, too. 16 MS. PARFITT: Objection to form. 16 Q. You don't disagree that Cramer, in his 17 A. I did not ask the causal question about 17 study, 2016, did find no apparent risk associated 18 that. And, you know, I have not evaluated. 18 with nongenital talc use; correct? 19 Maybe there are studies that show decreased risk 19 A. Yeah. 20 for all that I know. I just can't answer that 20 Q. The same result was found in the pooled analysis that was done by OCAC, Ovarian Cancer 21 question. 21 22 Association Consortium; is that right? 22 Q. And studies do not show an increase in MS. PARFITT: Objection. Which study 23 rectal cancer with talcum powder use; is that 23 24 24 are you referring to? What year? There have 25 been many studies by OCAC. 25 A. I don't answer the questions that I

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	Dama 210		Dama 220
_	Page 218		Page 220
1	MR. ZELLERS: I'm referring to Page 341	1	mechanisms that have been shown in terms of
2	of the Cramer article. Page strike that.	2	increase in, you know, inflammatory enzymes, and
3	The second and third paragraphs.	3	increase in alterations of redox potential that
4	BY MR. ZELLERS:	4	are some of the potential plausible biological
5	Q. Tell me when you have that, Doctor.	5	mechanisms. Again, other people who are
6	A. 341. Discussion?	6	biological experts will opine on them and detract
7	Q. Yes. So in the second and third	7	from the strengths and weaknesses.
8	paragraph, I'm reading the second sentence.	8	Q. You have not done an expert review of
9	"Talc use regularly" strike that.	9	inflammation evidence yourself; correct?
10	"Talc used regularly in the genital area was	10	A. When you say I mean, expert review
11	associated with a 33 percent increase in ovarian	11	of inflammation.
12	cancer risk overall while no apparent risk was	12	MS. PARFITT: Object.
13	associated with talc used only in nongenital	13	Q. You're deferring to other experts on
14	areas."	14	the topic and subject of inflammation; is that
15	A. Yeah. And I agree with their opinion.	15	right?
16	Q. All right. Do you also agree with the	16	MS. PARFITT: Objection.
17	next sentence? "Our results are consistent with	17	A. Yeah. I mean, other experts, I mean, I
18	the recent pooled analysis from the OCAC which	18	can look at the evidence and see, A, one, that
19	reported that use of powder on genitals is	19	inflammation plays a role in cancer. Two,
20	associated with a 24 percent increased risk and	20	inflammation plays a role in ovarian cancer.
21	no effect of nongenital use of talc."	21	At least my opinion is that, you know, talc
22	A. Yeah.	22	can, you know, induce inflammation; others will
23	Q. Have you ever performed any study	23	provide more detailed opinion.
24	yourself pertaining to whether inhaled talc can	24	Q. In terms of the mechanism by which
25	migrate to the ovaries?	25	ovarian cancer may or may not be related to
	Page 219		Page 221
1	A. No. And I would have a different job.	1	inflammation, you are deferring to other experts;
2			
	That's not my area of expertise.	2	correct?
3	That's not my area of expertise.  Q. And you can't, as we sit here, cite me	2 3	
3 4			correct?
	Q. And you can't, as we sit here, cite me	3	correct?  MS. PARFITT: Objection. Misstates his
4	Q. And you can't, as we sit here, cite me to such a study; correct?	3 4	correct?  MS. PARFITT: Objection. Misstates his testimony. He just told you
4 5	<ul> <li>Q. And you can't, as we sit here, cite me to such a study; correct?</li> <li>A. Well, I don't know if it's I'll go back to my report and just cite that that</li> <li>Dr. Luongo, you know, has done analyses which say</li> </ul>	3 4 5	correct?  MS. PARFITT: Objection. Misstates his testimony. He just told you  MR. ZELLERS: I'm asking him the question. Okay?  MS. PARFITT: Counsel, he did answer
4 5 6	<ul><li>Q. And you can't, as we sit here, cite me to such a study; correct?</li><li>A. Well, I don't know if it's I'll go back to my report and just cite that that</li></ul>	3 4 5 6	correct?  MS. PARFITT: Objection. Misstates his testimony. He just told you  MR. ZELLERS: I'm asking him the question. Okay?  MS. PARFITT: Counsel, he did answer it. And you just asked the question again and
4 5 6 7	<ul> <li>Q. And you can't, as we sit here, cite me to such a study; correct?</li> <li>A. Well, I don't know if it's I'll go back to my report and just cite that that</li> <li>Dr. Luongo, you know, has done analyses which say</li> </ul>	3 4 5 6 7	correct?  MS. PARFITT: Objection. Misstates his testimony. He just told you  MR. ZELLERS: I'm asking him the question. Okay?  MS. PARFITT: Counsel, he did answer
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56 (Pages 218 to 221)

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	e.
5 then that would be evidence against the link 5 Did I state that? You know, this is a chrore	ic
6 between redox potential and talc and ovarian 6 inflammatory process.	
7 cancer. So there are various pieces of the 7 Q. What evidence is there that external	ly
8 evidence. 8 applied talcum powder causes chronic	
9 Q. All of us experience inflammatory 9 inflammation?	
10 reactions of one sort or another, including 10 A. Yeah. I mean, you know can yo	give
chronic conditions, and they do not all lead to 11 me a second?	
12 cancer; correct? 12 Q. Sure.	
13 MS. PARFITT: Objection. Form. 13 A. Yeah. I'm not aware of a study that	
14 A. Yeah. But it's the balance of you 14 talc specifically itself causes chronic	
15 know, that is altered between pro-inflammatory 15 inflammation.	
and anti-inflammatory conditions and the Q. There are no reports in the literatur	;
pro-oxidant state and the antioxidant state in my 17 of externally applied talc leading to	
18 understanding that, you know, is a plausible 18 inflammation, granulomas, fibrosis or adh	
19 mechanism for talc in ovarian cancer. Again, 19 anywhere along a woman's reproductive tr	ict;
20 based on my understanding. Others will provide 20 correct?	
21 details. 21 MS. PARFITT: Objection.	
Q. Rheumatoid arthritis is an inflammatory 22 A. Yeah. There are other studies that,	
23 condition; right? 23 you know, not externally applied.	
A. Heart disease is everything is 24 Q. If up to 50 percent of U.S. women	
25 inflammation. 25 used genital talc, shouldn't this be a comm	

57 (Pages 222 to 225)

1 finding? 2 MS. PARFITT: Objection. Form. 3 A. So I'll step back and share with you what epidemiology. 4 what epidemiology. 5 Yeah. I mean, ovarian cancer, the incidence of orvarian cancer is, what, 11 by 100,000. It's a very rare cancer. Even if 50 percent use it, you know, it infereases, you know, it affects it. So we are not — nobody is saying that, you know, it infereases, you know, it affects it. So we are not — nobody is saying that, you know it of the U.S. population should get ovarian cancer is a different question. That's not what I estimated. 16 That's — you're asking a question about attributable risk and population attributable risk and po		Page 226		Page 228
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4 What cpidemiology.  Yeah. I mean, ovarian cancer, the incidence of ovarian cancer is, what, 11 by 100,000. It's a very rare cancer. Even if 50 percent use it, you know, it increases, you know, it affects it. So we are not — nobody is saying that, 10 yeah, every woman who gets tale will get it. So 11 just because there's an increased risk with tale, how much of the U.S. population should get ovarian cancer is afferent question. That's 10 ovarian cancer is afferent question. That's 11 on — is it Saed 2018 article?  A vest in the Pathogenesis of Ovarian Cancer is afferent question about a study that you do cite in support of your infalammation opinion. You rely on — is it Saed 2018 article?  A vest 12 ovarian cancer is afferent question about a study that you do cite in support of your infalammation opinion. You rely on — is it Saed 2018 article?  A vest 12 ovarian cancer is afferent question about a study that you do cite in support of your position. You rely on — is it Saed 2018 article?  A vest 13 ovarian cancer is different question about a study that you do cite in support of your position. You rely on — is it Saed 2018 article?  A vest 14 ovarian cancer is different question about a study that you do cite in support of your position. You rely on — is it Saed 2018 article?  A vest 2018 paper.  A vest	3		3	
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Page 230  A. So is this the study or is this just their review article?  Q. This is the paper that you cite to in your report.  A. Can you point out in my report which reference number is that? I know I've cited  Page  1 users?  A. Yeah. So I don't know if that's consistently. But as I mentioned earlier, and I may have cited it in this study, that when I talked about Ness, and I'm trying to find it, but, yes, there is, you know, NSAIDs have not	43 <i>4</i>
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6 reference number is that? I know I've cited 6 but, yes, there is, you know, NSAIDs have not	
7 them, but I'm just trying to orient myself. 7 been they don't consistently reduce the risk	
8 Q. Are you familiar with this paper? Have 8 of ovarian cancer, but in some studies, they hav	,
9 you looked at it before? 9 shown to reduce the risk of ovarian cancer.	•
10 A. Yes. I have looked at this paper, but 10 Q. If, in fact, inflammation was a	
they also have other abstracts and other papers. 11 causative factor in ovarian cancer, and if NSAI	)s
12 I think that's what I was relying on. 12 and aspirin use reduce inflammation, wouldn't	
Yeah. So I'm relying on this and 125, Saed. 13 expect some consistency in the studies that wou	
Q. The authors in this paper that you 14 show NSAIDs and aspirin use reduced the incident	ence
support strike that that you cite and are 15 of ovarian cancer?	
relying on do not identify what either the L6 A. So, first of all, you're asking a broad	
positive or the negative controls were; correct? 17 question. Inflammation. What do you mean by	
MS. PARFITT: Objection. Misstates the 18 that?	
19 evidence. 19 And I don't know yeah. Exactly. So I	
A. Let me just look at 125, and then I'll 20 don't know the precise biological mechanisms of	f
21 answer the question. 21 ovarian cancer. And just because the ovarian	
No. That's not 125.  22 cancer-mediated inflammation is different from	
Q. I'll move on and ask another question. 23 you know, anti-inflammatory, so both may be	
A. Sorry about that.  24 entirely consistent, I'm not saying they are, but	
25 Q. That's all right. 25 both mechanisms, you could have NSAID-indu	cea
Page 231 Page	233
1 Saed references unpublished data; correct? 1 reduce inflammation and NSAID-induced inc	ease
2 MS. PARFITT: Objection. 2 inflammation. That's just not what that area	
3 A. Yeah. And I've just been informed by 3 where other people will provide, you know, n	ore
4 counsel that it has been accepted for 4 testimony.	
5 publication, but the data that I that I 5 Q. If inflammation is the issue, why would	1
6 referenced were, you know, at the time, available 6 cornstarch be a superior alternative to tale?	
7 as abstracts. 7 MS. PARFITT: Objection. Form.	
8 Q. Saed referenced references 8 Q. And to give you context, the FDA ban	
9 unpublished data that you rely on in coming up 9 the use of cornstarch on surgical gloves becau	se
with at least some of the opinions in your  10 of the risk of inflammation, granulomas,  11 fibrois adherions and imitation; is that	
11 report; is that right?  11 fibrosis, adhesions and irritation; is that 12 A. Yeah. I mean, it's one of the, you 12 right?	
12 A. Yean. I mean, it's one of the, you 12 right?  13 know, number of studies that I reviewed. It's 13 A. I'm not aware of all the particular,	
not the only study on, you know, on biological 14 you know, regulatory actions on cornstarch.	
15 mechanisms. 15 Q. Take a look at the FDA 21 C.F.R, part	
16 Q. Why doesn't inflammation generally, for 16 878, 880, and 895.	
example, in pelvic inflammatory disease, cause 17 MR. ZELLERS: We'll mark that as	
18 ovarian cancer? 18 Deposition Exhibit 27.	
19 A. Again, that's not you know, that is 19 (Federal Register, Vol. 81, No.	
20 not I'm not going to be opining on the precise 20 243 marked Exhibit 27.)	
mechanisms of ovarian cancer in my testimony or 21 BY MR. ZELLERS:	
my report. That's not my area of expertise. 22 Q. If you look at the second page, first	
Q. Why don't NSAIDs and aspirin use, which 23 paragraph, last sentence, so I'm under executi	e
supposedly reduce inflammation, consistently 24 summary. The last sentence in the last full	
reduce the incidence of ovarian cancer in chronic 25 paragraph.	

	Page 234		Page 236
1	"However, the use of powder on medical	1	is that right?
2	gloves presents numerous risks to patients and	2	A. I don't disagree what I am trying to
3	healthcare workers, including inflammation,	3	define precisely confounding is that, you know,
4	granulomas, and respiratory allergic reactions."	4	it creates a different relationship, had the
5	Did I read that right?	5	confounder not been present, and I'm just trying
6	A. Yeah.	6	to say how it does that.
7	MS. PARFITT: Do you know where it is?	7	It's associated with the outcome. It's
8	Mm-hmm.	8	associated with the exposure and not, you know,
9	A. Okay.	9	and not on the
10	Q. Why, then, given that, would cornstarch	10	Q. Let's use an example, so we're sure
11	be considered a superior alternative to tale?	11	we're talking about the same thing.
12	MS. PARFITT: Objection. Form.	12	If you are studying the association between
13	A. Am I did I state in my I mean,	13	coffee and pancreatic cancer, you need to be
14	you know, I'm not evaluating the causal role of	14	mindful of whether cigarette smoking is more
15	cornstarch and, you know, its role in ovarian	15	common in coffee drinkers than in the rest of the
16	cancer. I'm not even aware of the existence of	16	population; correct?
17	this document and what it pertains to.	17	A. Yes.
18	I don't see any reference to cornstarch	18	Q. Cigarette smoking could be a confounder
19	here. I don't evaluate how they regulate various	19	in that situation; is that true?
20	products, whether it's food or cornstarch.	20	A. Well, so there are several parts to
21	Q. Are you familiar with the term	21	that. Just because it's more common in coffee
22	"confounding"?	22	drinkers does not make it a confounder. To make
23	A. Yes.	23	a confounder, you have to have three specific.
24	Q. That's where the presence of another	24	What you're talking is, yeah, it's associated
25	association confuses the relationship between the	25	with coffee. But is it associated with
	D 225		Davis 227
	Page 235		Page 237
1	exposure and disease being studied; correct?	1	pancreatic cancer? Is it on the causal pathway?
2	A. I don't I don't think that's the	2	So a confounder is a very precise
3	definition of confounding.	3	epidemiologic term. It's not just everything we
4	Q. What is wrong with that definition?	4	pull off the air and say because it's associated
5	A. Confusion is not an epidemiologic term.	5	with the coffee, it becomes a confounder.
6	There's no such thing as confusion in	6	Q. Listen to my question.
7	epidemiology. You have bias. You have	7	A. Sure.
8	misclassification. You have measurement error.	8	Q. Cigarette smoking could be a confounder
9	Confounding is a case where you have a	9	in my hypothetical; right?
10	variable that's related to the outcome and	10	A. If it was associated with pancreatic
11	that's, you know, maybe associated with the	11	cancer and not present in the causal pathway and,
12	exposure and is not on the causal pathway between	12	obviously, associated with coffee.
		13	Q. Because if more coffee drinkers are
13	exposure and outcome.	1	
14	And, you know, it creates an artifactual	14	smokers than non-coffee drinkers
14 15	And, you know, it creates an artifactual relationship between exposure and outcome.	14 15	smokers than non-coffee drinkers A. It could be the other way around.
14	And, you know, it creates an artifactual relationship between exposure and outcome.  Q. Confounding and confusion are similar	14 15 16	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee
14 15 16 17	And, you know, it creates an artifactual relationship between exposure and outcome.  Q. Confounding and confusion are similar terms; correct?	14 15 16 17	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to
14 15 16 17 18	And, you know, it creates an artifactual relationship between exposure and outcome. Q. Confounding and confusion are similar terms; correct? A. No. They're not. Confounding is a	14 15 16 17 18	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to smoking and not the coffee drinking; correct?
14 15 16 17	And, you know, it creates an artifactual relationship between exposure and outcome. Q. Confounding and confusion are similar terms; correct? A. No. They're not. Confounding is a scientific term. Confusion is layman from that.	14 15 16 17 18 19	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to smoking and not the coffee drinking; correct? A. Yes.
14 15 16 17 18 19	And, you know, it creates an artifactual relationship between exposure and outcome. Q. Confounding and confusion are similar terms; correct? A. No. They're not. Confounding is a scientific term. Confusion is layman from that. I don't think it has at least in my term, I	14 15 16 17 18 19 20	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to smoking and not the coffee drinking; correct? A. Yes. Q. Confounding can distort results in
14 15 16 17 18 19 20	And, you know, it creates an artifactual relationship between exposure and outcome. Q. Confounding and confusion are similar terms; correct? A. No. They're not. Confounding is a scientific term. Confusion is layman from that. I don't think it has at least in my term, I don't	14 15 16 17 18 19 20 21	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to smoking and not the coffee drinking; correct? A. Yes. Q. Confounding can distort results in epidemiological studies; is that right?
14 15 16 17 18 19 20 21	And, you know, it creates an artifactual relationship between exposure and outcome.  Q. Confounding and confusion are similar terms; correct?  A. No. They're not. Confounding is a scientific term. Confusion is layman from that. I don't think it has at least in my term, I don't  Q. So you disagree that confounding	14 15 16 17 18 19 20 21	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to smoking and not the coffee drinking; correct? A. Yes. Q. Confounding can distort results in epidemiological studies; is that right? A. Yes. And you have to adjust for
14 15 16 17 18 19 20 21 22 23	And, you know, it creates an artifactual relationship between exposure and outcome.  Q. Confounding and confusion are similar terms; correct?  A. No. They're not. Confounding is a scientific term. Confusion is layman from that. I don't think it has at least in my term, I don't  Q. So you disagree that confounding relates to the presence of another association	14 15 16 17 18 19 20 21 22 23	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to smoking and not the coffee drinking; correct? A. Yes. Q. Confounding can distort results in epidemiological studies; is that right? A. Yes. And you have to adjust for confounding.
14 15 16 17 18 19 20 21	And, you know, it creates an artifactual relationship between exposure and outcome.  Q. Confounding and confusion are similar terms; correct?  A. No. They're not. Confounding is a scientific term. Confusion is layman from that. I don't think it has at least in my term, I don't  Q. So you disagree that confounding	14 15 16 17 18 19 20 21	smokers than non-coffee drinkers A. It could be the other way around. Q. Exactly. An association between coffee drinking and pancreatic cancer might be due to smoking and not the coffee drinking; correct? A. Yes. Q. Confounding can distort results in epidemiological studies; is that right? A. Yes. And you have to adjust for

60 (Pages 234 to 237)

	Page 238		Page 240
1	MS. PARFITT: Objection.	1	But most importantly, just because, A, first
2	A. Sorry. Can you repeat the question?	2	of all, are they associated with the outcome?
3	MS. PARFITT: Here it is.	3	Then you have to ask, are they causally
4	Q. Sure. Residual confounding is possible	4	associated, and they would have to be associated
5	in every observational study; correct?	5	with the exposure talc to be considered a
6	A. Observational. Yeah.	6	confounder, just because they're a risk factor.
7	It is possible; right? Is that what you	7	Every risk factor need not be controlled in a
8	said?	8	study. You have to be associated with the
9	Q. Yes.	9	exposure to, you know, consider the confounder.
10	A. Yeah. Residual confounding is possible	10	That is the precise definition of
11	because you can't measure, you know, every	11	confounding, is you have to be associated with
12	variable that you can think of.	12	the exposure. You have to be associated with the
13	Q. And unmeasured confounders may be	13	outcome. And you can't be on the path.
14	present in every observational study; correct?	14	So just because chlamydia let me finish.
15	A. Yeah. There's always the potential for	15	Chlamydia, A, has a risk factor of ovarian
16	unmeasured confounding. It doesn't mean that it	16	cancer. If I design a study tomorrow for X and
17	exists.	17	ovarian cancer, you know, I'm not going to
18	Q. It's impossible to say that all known	18	consider it a confounder for my analysis.
19	and unknown confounding factors have been	19	Q. Confounders can distort the results in
20	controlled for in any given study; correct?	20	epidemiological studies; correct?
21	A. You don't you know, what you don't	21	MS. PARFITT: Objection. Form.
22	know, you can't control for.	22	A. Yeah. We've discussed that, I think.
23	Q. In this case, new factors possibly	23	THE WITNESS: We'll take a break. If
24	involved in ovarian cancer are just being	24	you want to finish this confounding thing.
25	published in the literature; is that right?	25	MR. ZELLERS: No. We can take a break
	Page 239		Page 241
1	MS. PARFITT: Objection. Vague.	1	now.
2	A. Yeah. I don't I don't know what	2	MS. PARFITT: Good. Thank you.
3	you're like just give me an example so I	3	THE VIDEOGRAPHER: This ends Media 3.
4	can	4	Off the record, 2:17 p.m.
5	Q. Okay. History of chlamydia infection	5	(A recess was taken.)
6	and history of weight gain during adolescence are	6	THE VIDEOGRAPHER: Here begins Media
7	two recent examples that are being published in	7	No. 4 in today's deposition of Sonal Singh, MD,
8	the literature as factors possibly involved with	8	M.P.H. Back on the record, 2:29 p.m.
9	ovarian cancer; correct?	9	BY MR. ZELLERS:
10	MS. PARFITT: Objection. Form.	10	Q. Dr. Singh, in your report, at Page 54,
11	A. I haven't seen them. But I mean,	11	Paragraph 7, you address the subject of
12	weight gain has been adjusted for in several of	12	confounding in studies of talcum powder use and
13	the analyses. So I don't know about that. Yeah.	13	ovarian cancer; is that right?
14	Q. Well, let's assume	14	A. Yes.
	A. We're talking about chlamydia.	15	Q. On Page 54 of your report, you state,
15	71. We're talking about emaily ara.	1	
15 16	Q. Let's assume that that's correct.	16	"Although there are some risk factors for ovarian
	<ul><li>Q. Let's assume that that's correct.</li><li>Those factors, history of chlamydia</li></ul>	16 17	cancer," and then it continues, "for any of them
16	Q. Let's assume that that's correct.  Those factors, history of chlamydia infection and history of weight gain during	17 18	cancer," and then it continues, "for any of them to be confounding to an extent that could account
16 17	Q. Let's assume that that's correct.  Those factors, history of chlamydia infection and history of weight gain during adolescence, those factors were not controlled	17 18 19	cancer," and then it continues, "for any of them to be confounding to an extent that could account for the positive relations that have been
16 17 18	Q. Let's assume that that's correct.  Those factors, history of chlamydia infection and history of weight gain during adolescence, those factors were not controlled for in any of the published talc-ovarian cancer	17 18 19 20	cancer," and then it continues, "for any of them to be confounding to an extent that could account for the positive relations that have been reported, they would have to be strongly
16 17 18 19	Q. Let's assume that that's correct.  Those factors, history of chlamydia infection and history of weight gain during adolescence, those factors were not controlled	17 18 19 20 21	cancer," and then it continues, "for any of them to be confounding to an extent that could account for the positive relations that have been reported, they would have to be strongly correlated with talc use. Family history,
16 17 18 19 20	Q. Let's assume that that's correct.  Those factors, history of chlamydia infection and history of weight gain during adolescence, those factors were not controlled for in any of the published talc-ovarian cancer studies, were they?  MS. PARFITT: Objection. Form.	17 18 19 20	cancer," and then it continues, "for any of them to be confounding to an extent that could account for the positive relations that have been reported, they would have to be strongly
16 17 18 19 20 21	Q. Let's assume that that's correct.  Those factors, history of chlamydia infection and history of weight gain during adolescence, those factors were not controlled for in any of the published talc-ovarian cancer studies, were they?	17 18 19 20 21 22 23	cancer," and then it continues, "for any of them to be confounding to an extent that could account for the positive relations that have been reported, they would have to be strongly correlated with talc use. Family history, ethnicity, obesity and some reproductive risk factors are positively associated with the risk
16 17 18 19 20 21	Q. Let's assume that that's correct.  Those factors, history of chlamydia infection and history of weight gain during adolescence, those factors were not controlled for in any of the published talc-ovarian cancer studies, were they?  MS. PARFITT: Objection. Form.	17 18 19 20 21 22	cancer," and then it continues, "for any of them to be confounding to an extent that could account for the positive relations that have been reported, they would have to be strongly correlated with talc use. Family history, ethnicity, obesity and some reproductive risk

	Page 242		Page 244
1		1	
2	introduce enough confounding either jointly to	1 2	Cancer"; is that right?
3	explain completely the positive associations."  And it should be the positive association.	3	A. If I haven't, then I haven't. Yeah. Q. You did put it on your additional
4	-		materials and data considered.
5	A. Yes.	4 5	
6	<ul><li>Q. Is that the statement that you make?</li><li>A. Yes.</li></ul>	6	Do you see that? A. Yes.
7	Q. There's no citation for that statement;	7	
8		8	Q. It's on the last page.
9	is that right?  A. Yes. But partly because I couldn't	9	MR. ZELLERS: I'm going to mark that
10	find evidence and, you know, about the risk of	10	paper as Exhibit 28. (Document entitled
11	talcum powder use and these risk factors. And so	11	"Interpretation of Epidemiologic Studies on
12	that so the issue that I prior to the	12	Talc and Ovarian Cancer" marked
13	statement, states that these other risk	13	Exhibit 28.)
14	factors, which we know are risk factors for	14	· · · · · · · · · · · · · · · · · · ·
15	ovarian cancer.	15	MS. PARFITT: Thank you. MR. ZELLERS: You're welcome.
16		16	BY MR. ZELLERS:
17	Q. Is this your statement that you made here?	17	
18		18	<ul><li>Q. Do you see Exhibit 28 in front of you?</li><li>A. Yes.</li></ul>
19	A. Yeah. Let me just explain what I did here.	19	
20		1	Q. Exhibit 28 is an article prepared by
21	Q. That was a simple question.	20 21	Kenneth Rothman entitled "Interpretation of
22	A. Yeah. It is my statement.	22	Epidemiologic Studies of Talc and Ovarian Cancer."
23	<ul><li>Q. Have I read your statement?</li><li>A. Yes. But it is about the fact that we</li></ul>	23	
23 24		24	Is that right?
25	don't have, you know, family history, ethnicity, obesity and reproductive factors associated, but	25	A. Yes.
23	obesity and reproductive factors associated, but	25	Q. Take a look at Page 5 of that paper,
	Page 243		Page 245
1	these associations, as it relates to talc use, we	1	the second paragraph.
2	don't have data on how these to be considered	2	Do you see where
3	a confounder, they have to be associated with	3	A. Confounding, you're talking about?
4	talc use. We don't have data on that.	4	Q. Yes. Where Rothman discusses
		_	
5	Q. My question just is: Did you write	5	confounding?
5 6	Q. My question just is: Did you write that?		
		5	confounding?
6	that?	5 6	confounding?  A. Yeah. Q. Other than the list of four risk factors in parentheses, you just copied the
6 7	that? A. I did. Yeah.	5 6 7	confounding?  A. Yeah.  Q. Other than the list of four risk
6 7 8	that? A. I did. Yeah. Q. All right. Now, do you know who Ken	5 6 7 8	confounding?  A. Yeah. Q. Other than the list of four risk factors in parentheses, you just copied the
6 7 8 9	that? A. I did. Yeah. Q. All right. Now, do you know who Ken Rothman is?	5 6 7 8 9	confounding?  A. Yeah. Q. Other than the list of four risk factors in parentheses, you just copied the language from Dr. Rothman's article and pasted it
6 7 8 9 10	that? A. I did. Yeah. Q. All right. Now, do you know who Ken Rothman is? A. Yeah. He has written a textbook on	5 6 7 8 9	confounding?  A. Yeah. Q. Other than the list of four risk factors in parentheses, you just copied the language from Dr. Rothman's article and pasted it into Page 54 of your report; correct?
6 7 8 9 10 11	that? A. I did. Yeah. Q. All right. Now, do you know who Ken Rothman is? A. Yeah. He has written a textbook on epidemiology. Q. He is a well-respected epidemiologist; is that right?	5 6 7 8 9 10 11	confounding?  A. Yeah. Q. Other than the list of four risk factors in parentheses, you just copied the language from Dr. Rothman's article and pasted it into Page 54 of your report; correct?  MS. PARFITT: Objection.  A. No. Q. All right. Do you have your report in
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6 7 8 9 10 11 12 13 14 15 16	that? A. I did. Yeah. Q. All right. Now, do you know who Ken Rothman is? A. Yeah. He has written a textbook on epidemiology. Q. He is a well-respected epidemiologist; is that right? A. Yeah. He's well respected. Q. He has written a textbook on epidemiology that's widely recognized as one of the best; is that right?	5 6 7 8 9 10 11 12 13 14 15 16 17	confounding?  A. Yeah.  Q. Other than the list of four risk factors in parentheses, you just copied the language from Dr. Rothman's article and pasted it into Page 54 of your report; correct?  MS. PARFITT: Objection.  A. No.  Q. All right. Do you have your report in front of you, Page 54?  A. And you say that I don't cite this article or  Q. If you don't cite that article, you have just testified under oath that these are your words in your report.
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6 7 8 9 10 11 12 13 14 15 16 17 18	that? A. I did. Yeah. Q. All right. Now, do you know who Ken Rothman is? A. Yeah. He has written a textbook on epidemiology. Q. He is a well-respected epidemiologist; is that right? A. Yeah. He's well respected. Q. He has written a textbook on epidemiology that's widely recognized as one of the best; is that right? MS. PARFITT: Objection. A. It is nice. I mean, I have a copy of	5 6 7 8 9 10 11 12 13 14 15 16 17 18	confounding?  A. Yeah.  Q. Other than the list of four risk factors in parentheses, you just copied the language from Dr. Rothman's article and pasted it into Page 54 of your report; correct?  MS. PARFITT: Objection.  A. No.  Q. All right. Do you have your report in front of you, Page 54?  A. And you say that I don't cite this article or  Q. If you don't cite that article, you have just testified under oath that these are your words in your report.
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	that? A. I did. Yeah. Q. All right. Now, do you know who Ken Rothman is? A. Yeah. He has written a textbook on epidemiology. Q. He is a well-respected epidemiologist; is that right? A. Yeah. He's well respected. Q. He has written a textbook on epidemiology that's widely recognized as one of the best; is that right? MS. PARFITT: Objection. A. It is nice. I mean, I have a copy of it. Q. I've looked at your report and your reliance list. In terms of your reliance list,	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	confounding?  A. Yeah.  Q. Other than the list of four risk factors in parentheses, you just copied the language from Dr. Rothman's article and pasted it into Page 54 of your report; correct?  MS. PARFITT: Objection.  A. No.  Q. All right. Do you have your report in front of you, Page 54?  A. And you say that I don't cite this article or  Q. If you don't cite that article, you have just testified under oath that these are your words in your report.  So take a look at Page 54 of your report.  Take a look at Page 5 of the Rothman paper.  A. Yeah. I mean, you know, I may have

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	Page 246		Page 248
1	MR. ZELLERS: Okay.	1	factors, family history, obesity and reproductive
2	A. I may have failed to cite that article.	2	history," what else is different? Show me one
3	You know, it's okay. I mean, it's not okay, but	3	word that is different
4	I'm just saying I may have failed to cite that	4	A. Yeah.
5	article.	5	Q between what you've written here and
6	Q. Do you agree that the entire first part	6	what is written by Rothman in his paper.
7	of Rothman on confounding that you have cited	7	A. Yeah. It isn't, and I should have
8	word for word in your report, and you can start	8	cited it.
9	with "although there have been some strong risk	9	Q. All right. The paper by Rothman and
10	factors for ovarian cancer, for any of them to be	10	others well, strike that.
11	confounding."	11	A. And where was this published, just I
12	A. Yeah.	12	mean, it doesn't have a citation in it.
13	Q. If you read the rest, all the way	13	Q. If you're going to copy it word for
14	through the next couple of sentences, down to	14	word
15	"positive association," it's	15	A. I did not.
16	A. Yeah.	16	MS. PARFITT: Excuse me. Object to the
17	Q word for word; right?	17	question. Don't be argumentive, Counsel. He
18	A. Yeah. I wouldn't say I copy and	18	said he didn't cut and paste it. He said he
19	pasted. I would say that I have not referenced	19	failed to cite it. That's his testimony.
20	it.	20	A. You can, you know, go forward and say
21	Q. You copied and pasted it.	21	that.
22	A. No. I did not. I read it, and I wrote	22	Q. The question is: You don't know let
23	it. And I did not reference it.	23	me withdraw that. You're looking at something.
24	Q. You didn't write it. It's exactly word	24	A. Yeah. Go ahead and ask the question.
25	for word from the Rothman paper	25	Q. You thought that this was a reliable
	Page 247		Page 249
1	A. No. It isn't.	1	source; correct?
2	Q with the exception of you added, in	2	A. Yes. And I did not cite it.
3	parentheses	3	Q. The Rothman paper, Exhibit 28?
4	A. Yeah.	4	A. Yes.
5	Q "genetic risk factors, family	5	Q. All right. Now
6	history, obesity and reproductive history"; is	6	A. Well, it's a source. I mean, it's in
7	that right?	7	with other source that I rely on.
8	A. Yeah. And I didn't cite it, but so	8	Q. At least in these couple of
9	you look at a study and a paper, and, you know, I	9	sentences
10	wrote it. And I was remiss in not citing it. I	10	A. In the paragraph.
11	didn't copy and paste it.	11	Q you agree; correct?
12	Q. Well, you copied it word for word;	12	A. Yeah.
13	correct?	13	MS. PARFITT: Agree what? Agree what?
14	A. I did not.	14	Q. Agree that the the two sentences
	MS. PARFITT: Objection. Misstates his	15	from Rothman are the same two sentences as in his
15		1 1 6	report and does he agree with those two
15 16	testimony.	16	report and does he agree with those two
		17	sentences?
16	testimony.		
16 17	testimony.  A. I'm saying what I did. But I did not	17	sentences?
16 17 18	testimony.  A. I'm saying what I did. But I did not cite it.	17 18	sentences?  A. Well, obviously, the risk factors are
16 17 18 19	testimony.  A. I'm saying what I did. But I did not cite it.  Q. The fact are the facts.	17 18 19	sentences?  A. Well, obviously, the risk factors are different, because I know more about the risk
16 17 18 19 20	testimony.  A. I'm saying what I did. But I did not cite it.  Q. The fact are the facts.  A. Well, the facts are that the content is	17 18 19 20	sentences?  A. Well, obviously, the risk factors are different, because I know more about the risk factors since 2000. And but the point that
16 17 18 19 20 21	testimony.  A. I'm saying what I did. But I did not cite it.  Q. The fact are the facts.  A. Well, the facts are that the content is different and I did not cite it.	17 18 19 20 21	sentences?  A. Well, obviously, the risk factors are different, because I know more about the risk factors since 2000. And but the point that I'm trying to make, and as you can see the
16 17 18 19 20 21	testimony.  A. I'm saying what I did. But I did not cite it.  Q. The fact are the facts.  A. Well, the facts are that the content is different and I did not cite it.  Q. What content is different other than	17 18 19 20 21 22	sentences?  A. Well, obviously, the risk factors are different, because I know more about the risk factors since 2000. And but the point that I'm trying to make, and as you can see the language is the same, and it should have been

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	Page 250		Page 252
-		1	
1	expert, to be fair and to cite information,	1	MS. PARFITT: No worries. No worries.
2	positions on that both support and refute your	2	A. Which line are you in there?
3	position and plaintiffs' position; correct?	3	Q. Sure. Look at "recall bias." Does the
4	A. Well, it's not about their position,	4	third sentence state, "Recall bias can readily
5	support or refute the causal hypothesis.	5	introduce enough bias to produce the modestly
6	And I'm agreeing that I was remiss in not	6	sized overall effect, relative risk equal 1.3,
7	citing this.	7	that emerges from these studies"?
8	Q. You also did not cite the next sentence	8	A. That's yeah, that's his
9	of Rothman	9	interpretation.
10	A. Yes.	10	Q. You don't disagree with that, do you?
11	Q which states, "Of course, it remains	11	A. Well, I do disagree in the sense that,
12	possible that yet unidentified risk factors for	12	you know, he's making inference on the magnitude.
13	ovarian cancer could be important confounders,	13	I'm not disagreeing that there's a potential for
14	and several such factors in the aggregate could	14	recall bias. But, you know, as I've discussed in
15	give risk to an overall association as weak as	15	my report and and, again, if you say that,
16	the one between talc and ovarian cancer."	16	then I should be writing the Rothman paper
17	You did not cite that; correct?	17	instead of my report. Right? You would want Ken
18	A. Yeah. And but that is already	18	Rothman to testify.
19	expressed. The same factor is also expressed in	19	You have to, you know, take you know, I
20	the first sentence. Confounding is one potential	20	understand what he's trying to say. He's saying
21	explanation for so, you know, again, if I had	21	that recall bias can introduce an element that
22	placed that sentence, you would say that, well,	22	would produce 1.3.
23	you're taking three lines, four.	23	Q. In fact, Rothman and the other authors
24	So I cite that confounding is one potential	24	of this paper conclude that the modest positive
25	explanation.	25	association
	Page 251		Page 253
1	Q. You don't disagree with that statement.		
	Q. Tou don't disagree with that statement.	1	A. Yeah.
2	A. Yeah. Yeah. Because that's one, you	2	A. Yeah. Q seen in epidemiological studies
2			
	A. Yeah. Yeah. Because that's one, you	2	Q seen in epidemiological studies
3	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential	2 3	Q seen in epidemiological studies could be explained by recall bias or an
3 4	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.	2 3 4	Q seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?
3 4 5	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.  Q. All right. Look at, if you will, on	2 3 4 5	<ul> <li>Q seen in epidemiological studies</li> <li>could be explained by recall bias or an</li> <li>unidentified confounding bias; correct?</li> <li>A. Yes.</li> </ul>
3 4 5 6	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.  Q. All right. Look at, if you will, on Page 1 of the Rothman paper, the middle paragraph. Rothman states, "Most of the published studies are interview-based,	2 3 4 5 6	<ul> <li>Q seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?</li> <li>A. Yes.</li> <li>Q. You did not note in your report Rothman's conclusion and if you turn to Page 8, his conclusion "More important, there</li> </ul>
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3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.  Q. All right. Look at, if you will, on Page 1 of the Rothman paper, the middle paragraph. Rothman states, "Most of the published studies are interview-based, case-control studies subject to recall bias which can readily give rise to associations of this magnitude."  Did I read that correctly?  A. Yes.  Q. Go to Page 4, third paragraph of the Rothman paper, Exhibit 28. I'm looking at the section under "recall bias," and the third	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?  A. Yes.  Q. You did not note in your report Rothman's conclusion and if you turn to Page 8, his conclusion "More important, there is also positive evidence against a causal association. The inverse dose-response trend for both duration of use and frequency of use, a pattern that could not be explained by a causal relation. Based on these considerations, we suggest that the evidence to date does not indicate that talc can be 'reasonably anticipated to be a human carcinogen.'"
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.  Q. All right. Look at, if you will, on Page 1 of the Rothman paper, the middle paragraph. Rothman states, "Most of the published studies are interview-based, case-control studies subject to recall bias which can readily give rise to associations of this magnitude."  Did I read that correctly?  A. Yes.  Q. Go to Page 4, third paragraph of the Rothman paper, Exhibit 28. I'm looking at the section under "recall bias," and the third sentence, "Recall bias can easily introduce	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?  A. Yes.  Q. You did not note in your report Rothman's conclusion and if you turn to Page 8, his conclusion "More important, there is also positive evidence against a causal association. The inverse dose-response trend for both duration of use and frequency of use, a pattern that could not be explained by a causal relation. Based on these considerations, we suggest that the evidence to date does not indicate that talc can be 'reasonably anticipated to be a human carcinogen.'"  A. Yes. And this report was prepared on
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.  Q. All right. Look at, if you will, on Page 1 of the Rothman paper, the middle paragraph. Rothman states, "Most of the published studies are interview-based, case-control studies subject to recall bias which can readily give rise to associations of this magnitude."  Did I read that correctly?  A. Yes.  Q. Go to Page 4, third paragraph of the Rothman paper, Exhibit 28. I'm looking at the section under "recall bias," and the third sentence, "Recall bias can easily introduce enough bias to produce the modestly sized overall	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?  A. Yes.  Q. You did not note in your report Rothman's conclusion and if you turn to Page 8, his conclusion "More important, there is also positive evidence against a causal association. The inverse dose-response trend for both duration of use and frequency of use, a pattern that could not be explained by a causal relation. Based on these considerations, we suggest that the evidence to date does not indicate that talc can be 'reasonably anticipated to be a human carcinogen.'"  A. Yes. And this report was prepared on November 8, 2000. That's 20 years ago. And we
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.  Q. All right. Look at, if you will, on Page 1 of the Rothman paper, the middle paragraph. Rothman states, "Most of the published studies are interview-based, case-control studies subject to recall bias which can readily give rise to associations of this magnitude."  Did I read that correctly?  A. Yes.  Q. Go to Page 4, third paragraph of the Rothman paper, Exhibit 28. I'm looking at the section under "recall bias," and the third sentence, "Recall bias can easily introduce enough bias to produce the modestly sized overall effect, relative risk equals 1.3, that emerges	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?  A. Yes.  Q. You did not note in your report Rothman's conclusion and if you turn to Page 8, his conclusion "More important, there is also positive evidence against a causal association. The inverse dose-response trend for both duration of use and frequency of use, a pattern that could not be explained by a causal relation. Based on these considerations, we suggest that the evidence to date does not indicate that talc can be 'reasonably anticipated to be a human carcinogen.'"  A. Yes. And this report was prepared on November 8, 2000. That's 20 years ago. And we have many other studies subsequent to that
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.  Q. All right. Look at, if you will, on Page 1 of the Rothman paper, the middle paragraph. Rothman states, "Most of the published studies are interview-based, case-control studies subject to recall bias which can readily give rise to associations of this magnitude."  Did I read that correctly?  A. Yes.  Q. Go to Page 4, third paragraph of the Rothman paper, Exhibit 28. I'm looking at the section under "recall bias," and the third sentence, "Recall bias can easily introduce enough bias to produce the modestly sized overall effect, relative risk equals 1.3, that emerges from these studies."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?  A. Yes.  Q. You did not note in your report Rothman's conclusion and if you turn to Page 8, his conclusion "More important, there is also positive evidence against a causal association. The inverse dose-response trend for both duration of use and frequency of use, a pattern that could not be explained by a causal relation. Based on these considerations, we suggest that the evidence to date does not indicate that talc can be 'reasonably anticipated to be a human carcinogen.'"  A. Yes. And this report was prepared on November 8, 2000. That's 20 years ago. And we have many other studies subsequent to that talking about dose-response, several other
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yeah. Yeah. Because that's one, you know, it's stated that, you know, one potential explanation.  Q. All right. Look at, if you will, on Page 1 of the Rothman paper, the middle paragraph. Rothman states, "Most of the published studies are interview-based, case-control studies subject to recall bias which can readily give rise to associations of this magnitude."  Did I read that correctly?  A. Yes.  Q. Go to Page 4, third paragraph of the Rothman paper, Exhibit 28. I'm looking at the section under "recall bias," and the third sentence, "Recall bias can easily introduce enough bias to produce the modestly sized overall effect, relative risk equals 1.3, that emerges from these studies."  MS. PARFITT: The only correction	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q seen in epidemiological studies could be explained by recall bias or an unidentified confounding bias; correct?  A. Yes.  Q. You did not note in your report Rothman's conclusion and if you turn to Page 8, his conclusion "More important, there is also positive evidence against a causal association. The inverse dose-response trend for both duration of use and frequency of use, a pattern that could not be explained by a causal relation. Based on these considerations, we suggest that the evidence to date does not indicate that talc can be 'reasonably anticipated to be a human carcinogen.'"  A. Yes. And this report was prepared on November 8, 2000. That's 20 years ago. And we have many other studies subsequent to that talking about dose-response, several other understandings about biological mechanisms.
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64 (Pages 250 to 253)

	Page 254		Page 256
1	ovarian cancer.	1	cigarette smoking and BMI.
2	Q. What methodology did you use to rule	2	Q. That it did control for that?
3	out the effect of an unidentified confounding	3	A. Yeah.
4	bias or multiple unidentified confounding biases?	4	Q. All right. Show me where, in Gertig
	A. Yeah. So I mean, as the meta-analyses	5	2000, that they state that they did control for
5 6 7 8 9	have shown, there are no differences between	6	BMI and for cigarette smoking.
7	most of the studies show no differences between	7	A. "For age-adjusted analysis, we
8	adjusted and unadjusted estimates, suggesting	8	categorized values as oral contraceptive use,
9	that the potential for confounding is minimal.	9	tubal ligation, post-menopausal, cigarette
10	There is no way to rule out unmeasured	10	smoking and BMI."
11	confounding. And that's always a possibility.	11	Q. What page?
12	It doesn't mean that it exists.	12	A. That's two whatever that page is,
13	Q. As we discussed earlier, you did review	13	250. Yeah. That's my understanding.
14		14	
	the Gertig 2000 paper and cite it in your report;		If you look at Table 1, they do have, you
15	is that right?	15	know, cigarette smoking and whatnot. That's my
16	A. Yes.	16	understanding.
17	Q. On Page 48 of your report, you note	17	Q. Ter Riet 2013, you cite that in your
18	that Gertig 2000 found a statistically	18	report; is that right?
19	significant increased risk for ever talc use for	19	A. It is.
20	serous invasive cancers; correct?	20	Q. Terry 2013 did not adjust for a hormone
21	A. Let me just come to that section.	21	replacement therapy usage; correct?
22	Yes.	22	MS. PARFITT: Here is Ter Riet.
23	Q. Gertig did not control for BMI or for	23	A. Just let me go back to my report. This
24	cigarette smoking, did it?	24	is the Ter Riet meta-analysis?
25	A. And I'm writing age, duration of	25	Q. Yes. Ter Riet 2013, meta-analysis.
	Page 255		Page 257
1	contraceptive use, BMI, smoking status.	1	A. Okay.
_			A. Okay.
2	Can I look at the study? Sorry.		•
2 3	Can I look at the study? Sorry.  O. You're not wasting my time, are you?	2	Q. The question is: Did Ter Riet 2013
3	Q. You're not wasting my time, are you?	2 3	Q. The question is: Did Ter Riet 2013 adjust for hormone replacement therapy usage?
3 4	<ul><li>Q. You're not wasting my time, are you?</li><li>A. No. No. Because my writeup says that.</li></ul>	2 3 4	<ul><li>Q. The question is: Did Ter Riet 2013</li><li>adjust for hormone replacement therapy usage?</li><li>A. Ter Riet.</li></ul>
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65 (Pages 254 to 257)

	Page 258		Page 260
1	Q. Recall bias, it's a concern in every	1	talc exposure as part of larger questionnaires on
2	retrospective study; is that right?	2	other risk factors, minimizing the possibility of
3	A. Yeah, it is a potential concern in	3	recall bias."
4	design of studies where, you know, you're asking	4	Did you write that?
5	about past exposure.	5	A. Yes.
6	<ul> <li>Q. Recall bias can distort a scientific</li> </ul>	6	<ul> <li>Q. How does asking about other risk</li> </ul>
7	evaluation of whether an exposure is actually	7	factors minimize recall bias as to a particular
8	related to a disease; correct?	8	risk factor?
9	A. Yes.	9	A. Yeah. Because, you know, you're not
10	Q. For example, recall bias could distort	10	stimulating them to answer you know, if you're
11	results if women with ovarian cancer were more	11	asking them ten questions about, say so it's
12	likely to remember their exposure to talc than	12	like, well, were you you know, were you
13	women without ovarian cancer; correct?	13	active, were you using oral contraceptives, were
14	A. Yes. I mean, but the extent here is	14	you so if you are let me finish. Let me
15	quite minimal, because we don't see it with a	15	finish my explanation.
16	you know, for daily use, you know, the likely	16	You're introducing the question of talc use
17	magnitude is small. We've talked about that.	17	within ten different questionnaires, then you
18	You know, if recall bias was operational, we	18	minimize the possibility of recall bias for that
19	would see it with nongenital talc use. They	19	particular product versus you're asking talc
20	would be reporting that. And we would be seeing	20	alone.
21	it with other types of, you know, cancer beyond,	21	Q. On what literature are you relying to
22	you know, ovarian.	22	say that asking about other risk factors
23	So, yes, recall bias is a potential, but the	23	minimizes recall bias as to another risk factor?
24	likely magnitude is small.	24	A. I mean, that's just my general
25	Q. On Page 54, Paragraph 6 of your	25	understanding of epidemiology. And maybe, you
	D 250		
	Page 259		Page 261
1		1	
1 2	report do you have Page 54, Paragraph 6?	1 2	know yeah, it's not I don't know if it's
	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question,		know yeah, it's not I don't know if it's specific to talc usage. Just a general
2	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question, I disagree with Rothman. So just because it's in	2	know yeah, it's not I don't know if it's specific to talc usage. Just a general understanding of epidemiology, about, you know
2	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question,	2 3	know yeah, it's not I don't know if it's specific to talc usage. Just a general
2 3 4	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question, I disagree with Rothman. So just because it's in Rothman's study, doesn't mean that it's, you know	2 3 4	know yeah, it's not I don't know if it's specific to talc usage. Just a general understanding of epidemiology, about, you know yeah, recall bias.
2 3 4 5	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question, I disagree with Rothman. So just because it's in	2 3 4 5	know yeah, it's not I don't know if it's specific to talc usage. Just a general understanding of epidemiology, about, you know yeah, recall bias.  Q. Are you done?  A. Yeah.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question, I disagree with Rothman. So just because it's in Rothman's study, doesn't mean that it's, you know  Q. I have a new question. Are you ready? A. No. I mean, I have to finish my last question.  Q. I didn't ask you a question. A. Okay. Because we are still on the topic of recall bias. Q. I asked the question. A. Okay. Q. Recall bias could distort results of women with ovarian cancer were more likely to remember their exposure to talc than women without ovarian cancer; correct? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	know yeah, it's not I don't know if it's specific to talc usage. Just a general understanding of epidemiology, about, you know yeah, recall bias.  Q. Are you done?  A. Yeah. Q. All right. Let's look at the effects of recall bias in a study on talcum powder use in ovarian cancer.  Are you familiar with the Schildkraut 2016 study?  A. Yes. Q. That was one of the studies that you relied on in forming your opinions; is that right?  A. Yes.  MR. ZELLERS: Let's mark that study as Deposition Exhibit 29.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question, I disagree with Rothman. So just because it's in Rothman's study, doesn't mean that it's, you know  Q. I have a new question. Are you ready? A. No. I mean, I have to finish my last question. Q. I didn't ask you a question. A. Okay. Because we are still on the topic of recall bias. Q. I asked the question. A. Okay. Q. Recall bias could distort results of women with ovarian cancer were more likely to remember their exposure to talc than women without ovarian cancer; correct? A. Yes. Q. The next question is: Can you turn to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	know yeah, it's not I don't know if it's specific to talc usage. Just a general understanding of epidemiology, about, you know yeah, recall bias.  Q. Are you done?  A. Yeah. Q. All right. Let's look at the effects of recall bias in a study on talcum powder use in ovarian cancer.  Are you familiar with the Schildkraut 2016 study?  A. Yes. Q. That was one of the studies that you relied on in forming your opinions; is that right?  A. Yes.  MR. ZELLERS: Let's mark that study as Deposition Exhibit 29.  (Article entitled "Association
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question, I disagree with Rothman. So just because it's in Rothman's study, doesn't mean that it's, you know   Q. I have a new question. Are you ready?  A. No. I mean, I have to finish my last question.  Q. I didn't ask you a question.  A. Okay. Because we are still on the topic of recall bias.  Q. I asked the question.  A. Okay.  Q. Recall bias could distort results of women with ovarian cancer were more likely to remember their exposure to talc than women without ovarian cancer; correct?  A. Yes.  Q. The next question is: Can you turn to Page 54, Paragraph 6 of your report?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	know yeah, it's not I don't know if it's specific to talc usage. Just a general understanding of epidemiology, about, you know yeah, recall bias.  Q. Are you done?  A. Yeah. Q. All right. Let's look at the effects of recall bias in a study on talcum powder use in ovarian cancer.  Are you familiar with the Schildkraut 2016 study?  A. Yes. Q. That was one of the studies that you relied on in forming your opinions; is that right?  A. Yes.  MR. ZELLERS: Let's mark that study as Deposition Exhibit 29.  (Article entitled "Association between Body Powder Use and Ovarian Cancer:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	report do you have Page 54, Paragraph 6?  A. Yeah. Just to clarify on the question, I disagree with Rothman. So just because it's in Rothman's study, doesn't mean that it's, you know   Q. I have a new question. Are you ready?  A. No. I mean, I have to finish my last question.  Q. I didn't ask you a question.  A. Okay. Because we are still on the topic of recall bias.  Q. I asked the question.  A. Okay.  Q. Recall bias could distort results of women with ovarian cancer were more likely to remember their exposure to talc than women without ovarian cancer; correct?  A. Yes.  Q. The next question is: Can you turn to Page 54, Paragraph 6 of your report?  A. Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	know yeah, it's not I don't know if it's specific to talc usage. Just a general understanding of epidemiology, about, you know yeah, recall bias.  Q. Are you done?  A. Yeah. Q. All right. Let's look at the effects of recall bias in a study on talcum powder use in ovarian cancer.  Are you familiar with the Schildkraut 2016 study?  A. Yes. Q. That was one of the studies that you relied on in forming your opinions; is that right?  A. Yes.  MR. ZELLERS: Let's mark that study as Deposition Exhibit 29.  (Article entitled "Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology
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66 (Pages 258 to 261)

	Page 262		Page 264
1	Between Body Powder Use and Ovarian Cancer; The	1	that they used talc on their genitals was
2	African American Cancer Epidemiology Study";	2	34 percent; is that right?
3	correct?	3	A. Where is that? Yeah.
4	A. Yes.	4	Q. The percentage of cases, meaning women
5	Q. The study looked at, among other	5	with ovarian cancer, that said that they used
6	things, what impact, if any, lawsuit filings in	6	talc on their genitals was 36.5 percent; is that
7	2014 had on whether women recalled using talc in	7	right?
8	the past; correct?	8	A. I'm just looking at this. Give me a
9	A. Yeah. It examined the issue of	9	second.
10	stimulated reporting. And I note it in my	10	36 interview data after 2004?
11	report. I don't I don't discount that in my	11	Q. No. My question here is: For women
12	discussion of the Schildkraut study.	12	who were interviewed before 2014
13	Q. We'll call it Schildkraut. Can we do	13	A. Mm-hmm.
14	that?	14	Q the control, so women without
15	A. Whatever. I don't know.	15	ovarian cancer, they stated they used talc on
16	Q. The authors in that study, Exhibit 29,	16	their genitals, 34 percent; is that right?
17	thought that the publicity from lawsuits might	17	A. Yes.
18	influence the participants' recall of prior body	18	Q. For that same time period, women
19	powder use; is that right?	19	interviewed before 2014
20	MS. PARFITT: Objection.	20	A. Mm-hmm.
21	A. Yes. And I noted on Page 45 of my	21	Q with ovarian cancer that said that
22	report that although there was some evidence that	22	they used talc on their genitals was
23	there was more reporting after class action	23	36.5 percent.
24	lawsuits in 2014, recall bias alone is	24	A. Yes.
25	insufficient because there is a statistically	25	Q. Is that right?
	Page 263		Page 265
1	Page 263 significant risk both before and after 2014. But	1	Page 265 So roughly the same reporting of genital
1 2		1 2	
	significant risk both before and after 2014. But		So roughly the same reporting of genital
2	significant risk both before and after 2014. But the authors did, you know, think it was an	2	So roughly the same reporting of genital talc use between women with and without ovarian
2	significant risk both before and after 2014. But the authors did, you know, think it was an important thing to look at.	2 3	So roughly the same reporting of genital talc use between women with and without ovarian cancer occurred before the lawsuits were filed in
2 3 4	significant risk both before and after 2014. But the authors did, you know, think it was an important thing to look at.  Q. The authors looked at this and tried to	2 3 4	So roughly the same reporting of genital talc use between women with and without ovarian cancer occurred before the lawsuits were filed in 2014.
2 3 4 5	significant risk both before and after 2014. But the authors did, you know, think it was an important thing to look at.  Q. The authors looked at this and tried to study this; is that right?	2 3 4 5	So roughly the same reporting of genital talc use between women with and without ovarian cancer occurred before the lawsuits were filed in 2014.  MS. PARFITT: Objection.
2 3 4 5 6	significant risk both before and after 2014. But the authors did, you know, think it was an important thing to look at.  Q. The authors looked at this and tried to study this; is that right?  A. Yes.	2 3 4 5 6	So roughly the same reporting of genital talc use between women with and without ovarian cancer occurred before the lawsuits were filed in 2014.  MS. PARFITT: Objection. Q. Correct?
2 3 4 5 6 7	significant risk both before and after 2014. But the authors did, you know, think it was an important thing to look at.  Q. The authors looked at this and tried to study this; is that right?  A. Yes.  Q. All right. Go to Page 4, Table 2 of	2 3 4 5 6 7	So roughly the same reporting of genital talc use between women with and without ovarian cancer occurred before the lawsuits were filed in 2014.  MS. PARFITT: Objection. Q. Correct? A. I don't know the timing of lawsuits,
2 3 4 5 6 7 8	significant risk both before and after 2014. But the authors did, you know, think it was an important thing to look at.  Q. The authors looked at this and tried to study this; is that right?  A. Yes.  Q. All right. Go to Page 4, Table 2 of the Schildkraut paper. Tell me when you have it.	2 3 4 5 6 7 8	So roughly the same reporting of genital talc use between women with and without ovarian cancer occurred before the lawsuits were filed in 2014.  MS. PARFITT: Objection. Q. Correct? A. I don't know the timing of lawsuits, but yes, 2014.
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1 Q. For women with ovarian cancer, before the lawsuits were filed, 36.5 percent of them as aid they recalled using baby powder; correct? 4 A. Yes. 5 Q. But after the lawsuits were filed, the percent of women with ovarian cancer who said they used baby powder went up to 51.5 percent; is that right? 9 A. Yes. 10 Q. So after the lawsuits were filed, the percent of women with ovarian cancer who said they used baby powder went up to 51.5 percent; is that right? 11 percent of women with ovarian cancer who said they used baby powder jumped by over 40 percent; is is that right? 11	ngs, because nt increased dy actually d be there was no that right?
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5 Q. But after the lawsuits were filed, the 6 percent of women with ovarian cancer who said 7 they used baby powder went up to 51.5 percent; is 8 that right? 9 A. Yes. 9 A. Yes. 10 Q. So after the lawsuits were filed, the 11 percent of women with ovarian cancer who said 12 they used baby powder jumped by over 40 percent; 13 is that right? 14 MS. PARFITT: Objection. Form. 15 A. By 40 percent? Where is 40? 16 Q. A difference between the 36 17 A. 10 percent. It's 51 and 34. Right? 18 Q. It jumped I don't have a calculator. 19 A. You're subtracting 51 to 36 or 51 to 20 34? 21 Q. Well, there was 22 A. Sorry. 22 A. Sorry. 23 Q. That's okay. It's late. 24 There was a significant increase 25 A. There was an increase. 26 Page 267 27 Q from 36.5 percent before the 28 lawsuits were filed to 51.5 percent after; is 39 that right? 40 A. Yes. 51 Q. So, suddenly, women who had ovarian cancer started reporting a higher incidence of talc use than women had reported before 2014; is 40 that right? 41 A. Yes. There was 41 the absence of statistically significance, that can be indicative existing; correct? 41 A. Yes. There was 42 D. So, suddenly, women who had ovarian cancer started reporting a higher incidence of talc use than women had reported before 2014; is 41 that right? 42 A. Yes. There was 43 that right? 43 A. Yes. 44 C. Yeah. Suddenly, wow, we widence of stimulated 45 that right? 46 A. Yes. There was 47 there was 48 Is that what you state? 49 A. Yes. 40 C. Let's look at what the stury shows. So go to 49 A. Yeah. It correct it. Shoul was an excess risk, because there statistically significant risk; is the statistically significant risk; is the statistically significant risk; is the excess risk.  41 A. Yeal. The test for effect by year of interview was techniq particular estimate for above 40 Expendit A. Well, it should be correct excess risk.  42 D. It is not, and there is not statistically significant risk; is the statistically significant risk; is the many significant risk; is the stat	d be there was no that right?
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they used baby powder jumped by over 40 percent; is that right?  MS. PARFITT: Objection. Form.  A. By 40 percent? Where is 40?  A. By 40 percent? Where is 40?  A. By 40 percent. It's 51 and 34. Right?  A. I0 percent. It's 51 and 34. Right?  A. You're subtracting 51 to 36 or 51 to  Q. Well, there was  20 A Sorry.  A. There was an increase  A. There was an increase.  Page 267  Q. A your report is in error; is in error; is in strain increase of that right?  A. Well, it should be correct excess risk.  Q. It is not, and there is not a statistically significant risk; is the indicative excess risk.  MS. PARFITT: Objection is a trained by year of interview was techniq particular estimate for above for before 2014 was not significant increase  21 particular estimate for above for before 2014 was not significant increase  22 A. Sorry.  23 Q. That's okay. It's late.  24 odds ratio of 1.19 with a confide ranging from .87 to 1.63; is that right?  A. Yes.  D. That is not statistically significant risk; is the sta	
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that right?  A. Yes.  Q. So, suddenly, women who had ovarian cancer started reporting a higher incidence of talc use than women had reported before 2014; is that right?  MS. PARFITT: Objection. Form.  MS. PARFITT: Objection. Form.  A. Yes. There was there was incidence you know, evidence of stimulated  is that right?  A. Yes.  Q. In the absence of statistical significance, that can be indicative existing; correct?  MS. PARFITT: Objection.  A. Yeah. But, you know, I'm the study as a whole. That's just o	
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incidence you know, evidence of stimulated 11 stimulated reporting in that study,	opining on
12 reporting. But that is just one element of   12 Yeah. So there's an excess risk, w	ne element of
	ne element of you know.
recall bias. That's not completely what is being 13 same direction, but not statistically	ne element of you know. hich is in the
14 addressed in my statement on recall bias. This 14 significant.	ne element of you know. hich is in the
is evidence about stimulated reporting, which is Q. If the study had ended before	ne element of you know. hich is in the
one one spectrum of recall bias. 16 would have found no statistically s	ne element of you know. hich is in the re 2014, it
Q. It's at least an example of the	ne element of you know. hich is in the re 2014, it significant
potential effect of recall bias; correct? 18 cancer; is that right?	ne element of you know. hich is in the re 2014, it significant
19 A. Yes. 19 A. I'm not seeing the study. I	ne element of you know. hich is in the ore 2014, it significant er and ovarian
Q. All right. Go to Page 45 of your 20 interpret the whole study; right?	ne element of you know. hich is in the ore 2014, it significant er and ovarian
21 report, the last sentence. 21 Q. Well, based upon this data	ne element of you know. hich is in the ore 2014, it significant er and ovarian have to
22 A. Yes. 22 looked at	ne element of you know. hich is in the ore 2014, it significant er and ovarian have to
Q. "Although" and I'm quoting you. 23 A. Yeah.	ne element of you know. hich is in the ore 2014, it significant er and ovarian have to
24 "Although there was some evidence that there was Q had the study ended before the st	ne element of you know. hich is in the ore 2014, it significant er and ovarian have to that we just
25 more reporting of genital powder use after class 25 there was not a statistically significant	ne element of you know. hich is in the ore 2014, it significant er and ovarian have to that we just ore 2014,

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relationship between talcum powder use and ovarian cancer; correct?  MS. PARFITT: Objection. Misstates the data.  A. Yeah. There was an excess risk which was not statistically significant. But, you know, we are picking and choosing analysis by 8 2004. Again, we talked about we are choosing by duration. You can pick any one of these analyses 10 to cite it. You have to look at the cumulative evidence and the cumulative evidence from meta-analyses.  John MS. PARFITT: Object to the form.  A. No.  G. Did you consider any testing that found no asbestos?  A. Yeah. I Idid. I think I'm citing the FDA report in my assessment that there are studied about we are choosing by duration. You can pick any one of these analyses and the cumulative evidence from meta-analysis and the cumulative evidence is based on the meta-analysis and the cumulative evidence is based on the meta-analysis and the cumulative evidence is based on the meta-analysis and the cumulative evidence is based on the meta-analysis and the cumulative evidence is based on the meta-analysis and the cumulative evidence is based in dividual study. My weight of evidence is based on the meta-analysis and the cumulative evidence is based on the mita-analysis and the cumulative evidence is based on the mita-analysis and the cumulative evidence is based on the mita-analysis and the cumulative evidence is based on the mita-analysis in the constituence is based on the mita-analysis and the cumulative evidence is based on the mita-analysis in the canalyses.  Page 271  A. No. I arrived at my causal opinion in mits matter independent of, you know, some of the deposition testimony of the expension of the literature even suggests and shows that, and some of the literature even suggests and shows that, and some of the letterature in the products are contaminated with a shows that, and some of the letterature even suggests and shows that, and some of the letterature in the products are contaminated with a shows that, and some of the literature in the products are contaminated		Page 270		Page 272
2 ovarian cancer, correct? 3 MS. PARFITT: Objection. Misstates the 4 data. 4 A. No. 5 A. Yeah. There was an excess risk which 6 was not statistically significant. But, you 7 know, we are picking and choosing analysis by 8 2004. Again, we talked about we are choosing by 9 duration. You can pick any one of these analyses 10 to cite it. You have to look at the cumulative 11 evidence and the cumulative evidence from 12 meta-analyses. 13 Q. How did you account for this recall 14 bias in weighing the Schildkrant study? 15 MS. PARFITT: Object to the form. 16 A. So, again, I did not weigh once 17 individual study. My weight of evidence is based 18 on the meta-analysis, the biological studies, 19 animal studies, human studies. 20 animal studies, human studies. 21 So, you know, I point out the limitations of 22 the individual studies, as do the authors of the 23 meta-analyses. 24 Q. Are your opinions in this matter 25 dependent on talcum powder containing asbestos? 26 Q. Are you opinions in this matter 27 a. A. No. 1 arrived at my causal opinion 28 moth are the constituents of, you know, tulcum 29 powder products. 29 A. Yes. 30 A. No. 1 arrived at my causal opinion 31 powder products. 32 A. Yes. 33 A. Yes. 44 A. No. 45 A. Yes. 46 PARFITT: Object to the form. 46 FDA report in my assessment that there are 47 studies that suggests the – I don't know if it's an FDA report in my assessment that there are 48 that, correct? 4 A. No. 49 Proth. I id. I think I'm citing the 4 A. No. 49 Proth. I id. I think I'm citing the 4 A. No. 40 Proth. I id. I think I'm citing the 4 A. No. 41 Proth. I id. I think I'm citing the 4 A. No. 41 Proth. I id. I think I'm citing the 4 A. No. 41 Proth. I id. I think I'm citing the 4 A. No. 41 Proth. I id. I think I'm citing the 4 A. No. 41 Proth. I id. I think I'm citing the 4 A. No. 41 Proth. I id. I think I'm citing the 4 A. No. 42 If you have the rear alwassment that there are 4 studies that suggests the – I don't know if it's 4 A. No. 4 No. PARFITT: Object to not normalistic evidence 4 The meta-ana	1	relationship between talcum powder use and	1	reports for that.
4 A. No. 5 A. Yeah. There was an excess risk which 6 was not statistically significant. But, you 7 know, we are picking and choosing analysis by 8 2004. Again, we talked about we are choosing by 9 duration. You can pick any one of these analyses 10 to cite it. You have to look at the cumulative 11 evidence and the cumulative evidence from 12 meta-analyses. 13 Q. How did you account for this recall 14 bias in weighing the Schildkraut study? 15 MS. PARFITT: Object to the form. 16 A. So, again, I did not weigh one 17 individual studic, My weight of evidence is based on the meta-analysis and the cumulative evidence from meta-analysis and the cumulative evidence of meta-analysis and the cumulative evidence of from meta-analysis, the biological studies, as do the authors of the individual studies, as do the authors	2	ovarian cancer; correct?	2	Q. You have no personal expertise with
A. Yeah. There was an excess risk which was not statistically significant. But, you know, we are picking and choosing analysis by 2004. Again, we talked about we are choosing by duration. You can picking hand you of the sea analyses 10 to cite it. You have to look at the cumulative evidence and the cumulative evidence from meta-analyses. 3 Q. How did you account for this recall bias in weighing the Schildkraut study? 15 MS. PARFITT: Object to the form. 16 A. So, again, I did not weigh one 17 individual stude, Why weight of evidence is based 18 on the meta-analysis and the cumulative evidence 18 from meta-analysis, the biological studies, 20 animal studies, human studies. 21 So, you know, I point out the limitations of 22 the individual studes, sa do the authors of the 23 meta-analyses. 24 Q. Are your opinions in this matter 25 dependent on talcum powder containing asbestos? 26 Q. Are your opinions in this matter 27 dependent on talcum powder containing asbestos? 28 q. Are you opinions in this matter 29 dependent on talcum powder containing asbestos? 30 or, you know, or my understanding of the 40 constituents. But I asked to better understand 5 what are the constituents of, you know, talcum 5 powder products. 6 Q. Is it fair to say that you have not 6 Q. Is it fair to say that you have not 7 made any independent determination. 7 made any independent determination as to whether 8 or not the talcum powder products are containinated with 9 dashestos?  19 J. R. Yes. 10 D. O you believe that talcum powder that 11 does not contain asbestos causes ovarian cancer? 12 A. Yes. 13 MR. ZELLERS: Move to strike as 14 nonresponsive. I'm going to ask the question 15 again. 16 MR. ZELLERS: Move to strike as 17 nonresponsive. I'm going to ask the question 18 again. 19 more products with asbestos were not 19 true, would your opinions in this case change? 19 more products with asbestos very not 10 powder products with a	3	MS. PARFITT: Objection. Misstates the	3	,
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#### Page 274 Page 276 1 Exhibit 28 to the deposition of John Hopkins and than from communicating with plaintiffs' counsel? 2 2 Exhibit 47 to the deposition of Julie Pier were A. I'm not sure what -- so --3 3 exhibits that were created by plaintiffs' MS. PARFITT: I'm going to object to 4 4 attorneys? the form. 5 MS. PARFITT: Objection. Completely 5 Q. Sure. The source of data? 6 misstates the evidence in this case. 6 A. Like source of --7 A. You know. I asked for constituents. I 7 Q. I'm asking you if you know where the 8 don't know what -- who created what. So I mean, 8 data in those exhibits came from. 9 9 I'm not going to be able to answer that type of A. So I'll try to answer to the best of my 10 10 question, who created this. ability. 11 11 I was asked for, you know, what are the My understanding is that the data on J&J and 12 constituents, that can I learn more about this? 12 Imerys were from mines tested over the years, 13 Q. Outside of your work in litigation, do 13 ranging, you know, from several decades. And 14 14 that contained or -- you know, were contaminated you normally rely on documents created by 15 with asbestos, various fibers that were created. 15 advocates in order to evaluate epidemiological 16 data? 16 And the second was the Luongo report was 17 17 products that were purchased and that were tested MS. PARFITT: Objection. Again, 18 misstates the evidence as to origin of the 18 in the laboratory. So that's where the source. 19 Hopkins and Pier Exhibits 28 and 40. 19 I mean, I assume these other two sources. 20 20 You may answer. Q. Have you made any effort to investigate 21 A. Yeah. I mean, I do. As I said 21 the alternative explanations for the data in 22 22 earlier, I rely on our published data. And as those charts, Exhibit 28 and Exhibit 47? 23 the Health Canada approach states, that we rely 23 A. I mean --24 on whatever evidence becomes available, and, A, 24 MS. PARFITT: Objection. 25 is relevant to the particular testimony. 25 A. So, for example, I think that those Page 275 Page 277 1 And, importantly, just as my causal opinion 1 data are, as I said earlier, my causal opinion 2 2 was arrived at independent of the constitution of is -- is, you know, this is only a -- my causal 3 asbestos in talc, Health Canada also is unaware 3 opinion is only -- you know, this is only a small 4 of the presence of -- or at least, you know, they 4 link in my causal opinion between talc and 5 5 haven't assessed the presence of asbestos in ovarian cancer, and it's not predicated on the 6 talc, and they are, you know, both congruent. 6 presence of asbestos. 7 Q. Your testimony is that outside of your 7 I don't have the expertise to determine 8 work in litigation, that you normally do rely on 8 whether asbestos is present. 9 data and documents created by plaintiffs' 9 Q. I'm trying to make it a simple 10 10 counsel? question. I'm just trying to find out what you 11 MS. PARFITT: Objection. Form. Asked 11 did and what you did not do. 12 and answered. And misstates the evidence. 12 Did you make any effort to investigate the 13 13 A. So I, you know, rely on evidence that's alternative explanations for the data in the 14 available in terms of epidemiologic evidence. 14 charts which are marked as Exhibit 28 and 15 And my testimony on asbestos was based on testing 15 Exhibit 47? 16 and based on -- testing by -- based on some of, 16 A. So --17 you know, there are studies which suggest the 17 MS. PARFITT: Objection. 18 presence of asbestos. 18 A. What is 28, 47? 19 19 Q. Do you know where the data in MS. PARFITT: Yeah. Let's get them. 20 Exhibit 28 to Hopkins and Exhibit 47 to Pier came 20 Do you have a copy of them here to show --21 from? 21 MR. ZELLERS: No. 22 A. You know, I was seeing these were in 22 MS. PARFITT: You aren't going to show 23 various mines conducted. That's my 23 it to him? 24 understanding. 24 MR. ZELLERS: He cites to these in his 25 Q. Do you have an understanding, other 25 report.

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Page 278		Page 280
MS. PARFITT: Then let's get them.	1	knowledge on these issues; correct?
We'll get them. Give him a moment.	2	A. Yeah. I mean, for my purpose, you
	3	know, it was more an understanding of the
to answer this question.	4	constituents, whether that would provide, you
MS. PARFITT: Do you need them,	5	know, proof against biologic plausibility, proof
Dr. Singh?	6	for biologic plausibility.
THE WITNESS: Yes.	7	So, for example, you say, did I undertake
MS. PARFITT: Do you want to take a	8	attempts to understand the constituents? Yes. I
quick break?	9	mean, I was looking for, well, are there some
MR. ZELLERS: And I object. And this	10	antioxidants that, if you had some antioxidants
should not be time that gets charged me.	11	in that product, and I'm not aware of, or anti,
BY MR. ZELLERS:	12	you know, carcinogens and maybe these scientists
Q. My question simply is: Did he attempt	13	will be able to provide that.
to investigate any alternative causes. He can	14	Q. Did you ask counsel for plaintiffs for
either say yes, he can say no, or he can say I	15	any information or testimony from either J&J
don't recall.	16	company folks or Imerys scientists as to what the
A. Yes.	17	tests actually showed with respect to asbestos?
Q. All right. What did you do to	18	MS. PARFITT: Other than Exhibits 28
investigate alternative explanations?	19	and 47?
A. I mean, you know, I was looking at	20	A. I assume those testifying were J&J
the I was already looking at the published	21	scientists and Imerys, and they were speaking
literature, but beyond that, I was looking at	22	about those tests.
what are the alternate again, as I said, you	23	Q. My question is: Did you ask for any
know, my expertise in determining I'm not a	24	additional information?
mineralist that I can, you know, that I can	25	A. No. I mean, I asked as I said, I
Page 279		Page 281
determine that. And, again, I'm not opining that	1	asked about the causal question and I got what I
	1	got. We can go about it in various ways.
	1	Like did I ask again? No, I didn't. And I
		don't want any more documents.
*		Q. We'll try to shortcut this.
	6	Do you believe Luongo? You reviewed his
•	7	testimony; right?
	8	MS. PARFITT: Objection. Form.
	9	Go ahead.
	10	A. Yeah. It's like how do you believe,
		you know again, it's an area of expertise. He
	12	tests, you know, these products, you know, this
•	13	is not my area of experience. At least based on
Q. It's a hypothetical question.	14	his testing, there is presence of asbestos in
	15	my and provides additional support.
	16	Q. Did you look at any of the experts for
understanding of whatever I was provided and	17	the defendants who have opined to the opposite
cited there, my understanding was that there was	18	statement or the opposite?
asbestos present in there and, you know, other	19	MS. PARFITT: I think objection.
people can have different opinions and I think	20	A. I was told that the expert defendants
	0.1	•
mineralogists, geologists will	21	hadn't even been you know, haven't submitted
mineralogists, geologists will Q. Those are the	21	reports or haven't been, you know, opined on.
Q. Those are the	22	reports or haven't been, you know, opined on.
	MR. ZELLERS: We don't need to get them to answer this question.  MS. PARFITT: Do you need them, Dr. Singh?  THE WITNESS: Yes.  MS. PARFITT: Do you want to take a quick break?  MR. ZELLERS: And I object. And this should not be time that gets charged me. BY MR. ZELLERS:  Q. My question simply is: Did he attempt to investigate any alternative causes. He can either say yes, he can say no, or he can say I don't recall.  A. Yes.  Q. All right. What did you do to investigate alternative explanations?  A. I mean, you know, I was looking at the I was already looking at the published literature, but beyond that, I was looking at what are the alternate again, as I said, you know, my expertise in determining I'm not a mineralist that I can, you know, that I can  Page 279  determine that. And, again, I'm not opining that Dr. Luongo's report I mean, he will have to vouch for his report.  Q. Let me ask it a different way.  A. Yeah.  Q. If scientists from the J&J companies and Imerys scientists say that those tests don't actually show asbestos, it was just tremolite reported, for example, you have no expertise to dispute that; correct?  MS. PARFITT: Objection. Misstates the evidence in this case, entirely.  Do you want to ask him a hypothetical?  Q. It's a hypothetical question.  MS. PARFITT: It's a hypothetical.  A. Again, with my limited expertise and my understanding of whatever I was provided and	to answer this question.  MS. PARFITT: Do you need them, Dr. Singh?  THE WITNESS: Yes.  MS. PARFITT: Do you want to take a quick break?  MR. ZELLERS: And I object. And this should not be time that gets charged me. BY MR. ZELLERS: Q. My question simply is: Did he attempt to investigate any alternative causes. He can either say yes, he can say no, or he can say I don't recall. A. Yes. Q. All right. What did you do to investigate alternative explanations? A. I mean, you know, I was looking at the I was already looking at the published literature, but beyond that, I was looking at what are the alternate again, as I said, you know, my expertise in determining I'm not a mineralist that I can, you know, that I can  Page 279  determine that. And, again, I'm not opining that Dr. Luongo's report I mean, he will have to vouch for his report. Q. Let me ask it a different way. A. Yeah. Q. If scientists from the J&J companies and Imerys scientists say that those tests don't actually show asbestos, it was just tremolite reported, for example, you have no expertise to dispute that; correct? MS. PARFITT: Objection. Misstates the evidence in this case, entirely. Do you want to ask him a hypothetical? Q. It's a hypothetical question. MS. PARFITT: It's a hypothetical. A. Again, with my limited expertise and my understanding of whatever I was provided and

71 (Pages 278 to 281)

	Page 282		Page 284
1	MS. PARFITT: Objection. Misstates the	1	I'm not trying to slow you down.
2	heart of his testimony.	2	MR. TISI: And you said you think he
3	A. So, first of all, this report is 70	3	was.
4	whatever pages. Luongo is maybe a paragraph or	4	MR. ZELLERS: Yes. And it was in jest
5	two. So, yes, I believe that was one study.	5	Counsel. We all chuckled and we all laughed.
6	For the purposes of, you know, identifying,	6	MR. TISI: As long as it was in jest,
7	you know, I identified his. I identified what	7	that's fine.
8	was shown and what was in those notes. And I	8	THE WITNESS: I took it to be in jest.
9	identified some epidemiologic I mean, some	9	I know I reviewed one, but I'm just
10	findings in the published literature.	10	trying to see if I reviewed another one. There
11	I mean, that's as much as I could know about	11	was yeah.
12	it. I mean, you had Routers' study, you know,	12	So I said, No. 30 and then 31, 32, two
13	talking about it in the media. So there's lots	13	additional reports. Sorry.
14	of different things.	14	Q. Have you ever met Luongo?
15	I didn't go and, you know, go looking into	15	A. I don't know him.
16	the Routers report. Maybe that's what I should	16	Q. Do you know his qualifications?
17	be looking at.	17	A. No.
18	Q. You did not confirm that any of the	18	Q. Had you ever heard of him before you
19	talc samples mentioned in those charts were	19	got involved in this MDL talc ovarian cancer
20	actually from tale that was used in baby powder;	20	litigation?
21	correct?	21	A. No.
22	MS. PARFITT: Objection. Misstates the	22	Q. Have you reviewed any Luongo testing
23	evidence that was available to him. If you want	23	where he did not find asbestos?
24	to show him the charts, you can do it.	24	A. These were the three reports I
25	Q. Can you answer that question?	25	reviewed. So I don't know if he has conducted
	Control of the contro	25	reviewed. So I don't know if he has conducted
	Page 283	23	
1	Page 283	1	Page 28
	Page 283 MS. PARFITT: Objection.		Page 285 additional testing.
1	Page 283  MS. PARFITT: Objection.  A. I did not confirm it myself.	1	Page 285 additional testing.  Q. Let me ask again. Have you reviewed
1 2	Page 283  MS. PARFITT: Objection.  A. I did not confirm it myself.  Q. You realize that the vast majority of	1 2	Page 285 additional testing.
1 2 3 4	Page 283  MS. PARFITT: Objection.  A. I did not confirm it myself.  Q. You realize that the vast majority of talc isn't even used for body powder; correct?	1 2 3	Page 285 additional testing. Q. Let me ask again. Have you reviewed any Luongo testing where he did not find asbestos?
1 2 3	Page 283  MS. PARFITT: Objection.  A. I did not confirm it myself. Q. You realize that the vast majority of talc isn't even used for body powder; correct?  MS. PARFITT: Objection. Misstates the	1 2 3 4	Page 285 additional testing. Q. Let me ask again. Have you reviewed any Luongo testing where he did not find
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	Page 286		Page 288
1	is that any amount and I think there's some	1	at meta-analysis that, you know, cause, as well
2	testimony from others to that effect as well.	2	as the IARC report that, you know, talks about
3	But I'll defer to others.	3	asbestos and fibrous talc as a carcinogen and
4	Q. Do you have an opinion on what type of	4	also cites studies that show that asbestos causes
5	asbestos is in the baby powder products?	5	ovarian cancer. But, again, I wasn't doing a
6	A. Again, you know, this whole you	6	formal causal analysis.
7	know, this sort of questions around constituents	7	Q. Do you agree that research on the
8	of the product, for me, it was more trying to	8	potential relationship between asbestos and
9	understand whether it's asbestos or any other	9	ovarian cancer has only considered a small number
10	constituents in the product, provide evidence in	10	of cases?
11	support or against.	11	MS. PARFITT: Objection. Form.
12	I can't tell you what amount would cause or,	12	A. I mean, ovarian cancer is a rare, rare
13	you know, not cause baby in baby powder will	13	disease. And, you know, it's going to be a small
14	cause ovarian cancer.	14	number of cases, regardless of etiology, what
15	Q. What types of asbestos are associated	15	they are trying to study.
16	with ovarian cancer?	16	Q. How many of the studies involve
17	A. I haven't done a causal analysis of	17	occupational exposure?
18	asbestos and ovarian cancer. I know that the	18	A. I think the predominant
19	IARC has classified asbestos as a carcinogen,	19	MS. PARFITT: Objection.
20	Grade 1, and that also stated that it caused	20	A studies have involved occupational
21	ovarian cancer, but about asbestos and fibrous	21	exposure.
22	talc, but obviously others will provide more	22	Q. How many were nonoccupational, if any?
23	more specifics.	23	A. I don't recall the numbers.
24	Q. Do you have any strike that.	24	Q. Did any of the nonoccupational asbestos
25	Do you have knowledge as to the different	25	studies reach statistical significance?
	Page 287		Page 289
1	types of asbestos?	1	MS. PARFITT: Objection. Form.
2	A. No.	2	A. Again, I would have to look at the
3	Q. What dose of asbestos is associated	3	study that you're talking about. And I just I
4	with ovarian cancer?	4	can't recall it off the top of my head.
5	A. I have not evaluated the dose of	5	Q. Can you tell how many women were
6	asbestos with ovarian cancer.	6	studied?
7	Q. What type of ovarian cancer is asbestos	7	A. No, I can't. I mean, you can't ask
8	associated with?	8	questions about these things, and tell me how
9	A. I have not as I said earlier, I have	9	many women. No. You have to show me the study
10	not evaluated the specific causal link between	10	if you want to go down that line of questioning.
11	asbestos and ovarian cancer. My causal question	11	Q. I'll show you a study.
12	was, does talcum powder products cause ovarian	12	A. Sure.
13	cancer. And whatever the constituents are, you	13	Q. Are you familiar with the Reid study
14	know, whether they provide evidence in support or	14	published May 24th of 2011?
4 -	against. And, as you said, there may be	15	A. Yes.
15	agamst. That, as you said, there may be		Q. It's one of the studies you looked at;
15 16	additional testing.	16	Q. It's one of the studies you looked at,
		16 17	is that right?
16	additional testing.  Q. Does the type of ovarian cancer vary based upon the type of asbestos?		•
16 17	additional testing.  Q. Does the type of ovarian cancer vary based upon the type of asbestos?  A. Again, I didn't evaluate that that	17 18 19	is that right?
16 17 18	additional testing.  Q. Does the type of ovarian cancer vary based upon the type of asbestos?  A. Again, I didn't evaluate that that body of evidence.	17 18 19 20	is that right? A. Yes.
16 17 18 19	additional testing.  Q. Does the type of ovarian cancer vary based upon the type of asbestos?  A. Again, I didn't evaluate that that	17 18 19 20 21	is that right? A. Yes. MR. ZELLERS: We'll mark that as
16 17 18 19 20	additional testing.  Q. Does the type of ovarian cancer vary based upon the type of asbestos?  A. Again, I didn't evaluate that that body of evidence.  Q. Did you evaluate studies that have explored the potential link between asbestos and	17 18 19 20	is that right? A. Yes. MR. ZELLERS: We'll mark that as Exhibit 30. (Article entitled "Does Exposure to Asbestos Cause Ovarian Cancer? A
16 17 18 19 20 21 22 23	additional testing. Q. Does the type of ovarian cancer vary based upon the type of asbestos? A. Again, I didn't evaluate that that body of evidence. Q. Did you evaluate studies that have explored the potential link between asbestos and ovarian cancer?	17 18 19 20 21 22 23	is that right? A. Yes. MR. ZELLERS: We'll mark that as Exhibit 30. (Article entitled "Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and
16 17 18 19 20 21	additional testing.  Q. Does the type of ovarian cancer vary based upon the type of asbestos?  A. Again, I didn't evaluate that that body of evidence.  Q. Did you evaluate studies that have explored the potential link between asbestos and	17 18 19 20 21 22	is that right? A. Yes. MR. ZELLERS: We'll mark that as Exhibit 30. (Article entitled "Does Exposure to Asbestos Cause Ovarian Cancer? A

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	Page 290		Page 292
1	THE WITNESS: Can you repeat the	1	Where are you pointing to?
2	question for me?	2	MR. ZELLERS: Sure. I'm looking at
3	MR. ZELLERS: Sure.	3	the
4	THE WITNESS: I'm sorry.	4	MS. PARFITT: Thank you.
5	BY MR. ZELLERS:	5	MR. ZELLERS: No. 2.
6	Q. Go to the first page, the right column.	6	MS. PARFITT: Uh-huh.
7	A. Mm-hmm.	7	MR. ZELLERS: The last full sentence.
8	Q. Reid. And this article is entitled	8	MS. PARFITT: Thank you. I appreciate
9	"Does Exposure to Asbestos Cause Ovarian Cancer?"	9	it.
10	Is that right?	10	MR. ZELLERS: On Page first page of
11	A. Yes.	11	the article.
12	Q. The authors state, on the first page,	12	MS. PARFITT: Thank you. I appreciate
13	on the right-hand side, right above the No. 1 and	13	that.
14	No. 2, "Studies that have examined this issue	14	MR. ZELLERS: Sure.
15	have been limited for two major reasons. No. 1,	15	A. Yes.
16	small number of cases"; is that right?	16	Q. Have the studies addressed confounding
17	A. Yes.	17	and independent risk factors?
18	Q. The authors state, "Much fewer women	18	A. Well, again, you know, my examination
19	than men have been exposed to asbestos,	19	of asbestos I mean, I was not trying to
20	particularly in more heavily exposed occupational	20	establish a causal link between asbestos and
21	settings where relative risks are higher."	21	ovarian cancer, you know, when in trying to look
22	You agree with that; correct?	22	at talcum powder products and ovarian cancer, you
23	A. Yes.	23	know, one of the questions was constituents.
24	Q. Then the second major limitation deals	24	And, you know, the IARC agrees that, or at
25	with difficulties of diagnosis; is that right?	25	least opines that it is, causally, is a
			Page 293
1	A. Yes.	1	_
1 2		1 2	carcinogen and lists that and lists the Kamargo
3	Q. Are you aware of the difficulties that have existed over time in distinguishing between	3	study as, you know, that asbestos causes ovarian
4	peritoneal mesothelioma and ovarian cancer?	4	cancer.  O Well the Compared 2011 study.
5	A. Yes. As a general idea of you know,	5	Q. Well, the Camargo 2011 study
6	because they share histologic similarities.	6	acknowledges an inability to account for nonoccupational risk factors for ovarian cancer
7	Q. Did those difficulties affect the	7	other than age; correct?
8	reliability of the studies?	8	
	A. Yes, but if you look at Table 2 of that		A. Again, if I can
9 10	report, you see that, despite if you look at	9	<ul><li>Q. Take a look. Sure.</li><li>A. These statements it's getting to the</li></ul>
11	studies that review the ovarian pathology, you	11	end of the day, so
$\perp \perp$	studies that review the ovarian pathology, you	1 ++	cha of the day, so
	ctill see a statistically significant increased	1 2	MD 7ELLEDS: Danagition Exhibit 21
12	still see a statistically significant increased	12	MR. ZELLERS: Deposition Exhibit 31.
12 13	risk of incidence of mortality from ovarian	13	(Article entitled "Occupational
12 13 14	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher	13 14	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A
12 13 14 15	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account	13 14 15	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.)
12 13 14 15 16	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you	13 14 15 16	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS:
12 13 14 15 16 17	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that we still	13 14 15 16 17	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS: Q. Deposition Exhibit 31 is the Kamargo
12 13 14 15 16 17	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that we still are left with that asbestos causes, you know,	13 14 15 16 17 18	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS: Q. Deposition Exhibit 31 is the Kamargo paper; is that right?
12 13 14 15 16 17 18	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that we still are left with that asbestos causes, you know, ovarian cancer.	13 14 15 16 17 18 19	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS: Q. Deposition Exhibit 31 is the Kamargo paper; is that right? A. Yes.
12 13 14 15 16 17 18 19 20	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that we still are left with that asbestos causes, you know, ovarian cancer.  Q. The authors of the Reid paper that you	13 14 15 16 17 18 19 20	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS: Q. Deposition Exhibit 31 is the Kamargo paper; is that right? A. Yes. Q. This is another paper that you have
12 13 14 15 16 17 18 19 20 21	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that we still are left with that asbestos causes, you know, ovarian cancer.  Q. The authors of the Reid paper that you reviewed and relied on, Exhibit 30, stated, "It	13 14 15 16 17 18 19 20 21	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS: Q. Deposition Exhibit 31 is the Kamargo paper; is that right? A. Yes. Q. This is another paper that you have reviewed?
12 13 14 15 16 17 18 19 20 21 22	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that we still are left with that asbestos causes, you know, ovarian cancer.  Q. The authors of the Reid paper that you reviewed and relied on, Exhibit 30, stated, "It has been particularly difficult to distinguish	13 14 15 16 17 18 19 20 21 22	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS: Q. Deposition Exhibit 31 is the Kamargo paper; is that right? A. Yes. Q. This is another paper that you have reviewed? A. Yes.
12 13 14 15 16 17 18 19 20 21 22 23	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that we still are left with that asbestos causes, you know, ovarian cancer.  Q. The authors of the Reid paper that you reviewed and relied on, Exhibit 30, stated, "It has been particularly difficult to distinguish between peritoneal mesothelioma and ovarian	13 14 15 16 17 18 19 20 21 22 23	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS: Q. Deposition Exhibit 31 is the Kamargo paper; is that right? A. Yes. Q. This is another paper that you have reviewed? A. Yes. Q. On the first page, the overview
12 13 14 15 16 17 18 19 20 21	risk of incidence of mortality from ovarian cancer. So, yes, overall studies, it's a higher estimate, but even if you take into account mesothelioma diagnoses and misclassification, you still cannot, you know, account that we still are left with that asbestos causes, you know, ovarian cancer.  Q. The authors of the Reid paper that you reviewed and relied on, Exhibit 30, stated, "It has been particularly difficult to distinguish	13 14 15 16 17 18 19 20 21 22	(Article entitled "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-analysis" marked Exhibit 31.) BY MR. ZELLERS: Q. Deposition Exhibit 31 is the Kamargo paper; is that right? A. Yes. Q. This is another paper that you have reviewed? A. Yes.

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	Page 294		Page 296
1	monograph working group of IARC conducted" or	1	Q. And you're not making a causal
2	strike that "concluded that there is	2	assessment or determination
3	sufficient evidence for a causal association	3	A. No.
4	between exposure to asbestos and ovarian cancer.	4	Q on asbestos; is that right?
5	We performed a meta-analysis to quantitatively	5	A. Yes.
6	evaluate this association."	6	Q. Okay. Under "discussion," Page 1215
7	Is that right?	7	A. And I'm going to take a break after
8	A. Yes.	8	that whenever you're done. I'm sorry. I need to
9	Q. If you look at Page 1216, middle	9	use the restroom.
10	column are you there?	10	Q. That's okay. That's fine. That's
11	So I'm looking at the second full paragraph	11	fine.
12	above "conclusion."	12	Do you see under "discussion," this is on
13	"A further limitation of our analysis was	13	the left-hand column, second full paragraph,
14	its inability to account for nonoccupational risk	14	where they're talking about Edelman?
15	factors for ovarian cancer other than age."	15	A. Yes.
16	Do you see that?	16	Q. And the authors state, "They concluded,
17	A. And what do you mean by that? I mean,	17	however, that despite the positive and
18	I didn't again, you know, I	18	significant association, there was insufficient
19	Q. Let me just ask. Is that a	19	information to infer that ovarian cancers were
20	limitation	20	caused by occupational exposure to asbestos
21	A. Yeah.	21	because of concerns about tumor
22	Q on the analysis?	22	misclassification, inappropriate comparison
23	A. It is a limitation.	23	populations and the failure to take into account
24	Q. Hasn't failure to account for	24	for known risk factors."
25	misclassification and known risk factors been	25	Is that
	Page 295		Page 297
1	cited as a reason why causality cannot be	1	A. Again
2	established?	2	Q. You don't disagree with that, do you?
3	MS. PARFITT: Objection.	3	A. Yeah. I mean, I don't but I don't
4	A. We can't rely on IARC. As you said,	4	disagree I mean, I'm relying on the IARC
5	one said that it is possibly associated and here,	5	assessment and others that, you know, there's a
6	when they haven't arrived at a I mean,	6	causal association between exposure. Again, I
7	causality is just not about association in one.	7	did not review. I would have gotten and reviewed
8	I mean, they have to look at other biological	8	evidence, Edelman and White and others, if I had
9	mechanisms of asbestos and ovarian cancer, you	9	to do it over again.
10	know, what happens in the lab, what happens I	10	MR. ZELLERS: Let's take a break.
11	haven't done that evaluation.	11	We'll come back and I'll finish up. Thank you.
12	So, yes, this is a limitation. But this	12	THE VIDEOGRAPHER: Off the record,
13	needs to be taken into account with, you know,	13	3:32 p.m.
	the entire body of evidence on asbestos and	14	(A recess was taken.)
14	the entire body of evidence on assessos and	1	THE VIDEOGRAPHER: Here begins Media
	ovarian cancer.	15	
14		15 16	No. 5 in today's deposition of Sonal Singh, MD,
14 15	ovarian cancer.		No. 5 in today's deposition of Sonal Singh, MD, M.P.H. Back on the record, 3:43 p.m.
14 15 16	ovarian cancer.  Q. You're looking at and relying on papers, including Reid, Exhibit 30?  A. The IARC monographs.	16	M.P.H. Back on the record, 3:43 p.m. BY MR. ZELLERS:
14 15 16 17	ovarian cancer.  Q. You're looking at and relying on papers, including Reid, Exhibit 30?	16 17 18 19	M.P.H. Back on the record, 3:43 p.m.
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14 15 16 17 18 19	ovarian cancer.  Q. You're looking at and relying on papers, including Reid, Exhibit 30?  A. The IARC monographs.  Q. And Kamargo, Exhibit 31; is that right?	16 17 18 19	M.P.H. Back on the record, 3:43 p.m. BY MR. ZELLERS: Q. Dr. Singh, do you agree that exposure
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14 15 16 17 18 19 20 21	ovarian cancer.  Q. You're looking at and relying on papers, including Reid, Exhibit 30?  A. The IARC monographs.  Q. And Kamargo, Exhibit 31; is that right?  A. Yes. And, again, I'm clarifying that I'm not making a causal determination on IARC, you know. I'm just relying on that, you know, that I'm not first of all, I didn't set out to	16 17 18 19 20 21 22 23	M.P.H. Back on the record, 3:43 p.m. BY MR. ZELLERS: Q. Dr. Singh, do you agree that exposure to asbestos through perineal cosmetic talc use, assuming the talc contains asbestos fibers, is different than the heavy occupational exposure that's primarily been researched?
14 15 16 17 18 19 20 21	ovarian cancer.  Q. You're looking at and relying on papers, including Reid, Exhibit 30?  A. The IARC monographs.  Q. And Kamargo, Exhibit 31; is that right?  A. Yes. And, again, I'm clarifying that I'm not making a causal determination on IARC, you know. I'm just relying on that, you know,	16 17 18 19 20 21 22	M.P.H. Back on the record, 3:43 p.m. BY MR. ZELLERS: Q. Dr. Singh, do you agree that exposure to asbestos through perineal cosmetic talc use, assuming the talc contains asbestos fibers, is different than the heavy occupational exposure

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	Page 298		Page 300
1	be an expert in different kinds and routes of	1	may do testing and provide antioxidants and
2	asbestos exposure. My my sort of at least	2	substances which reduce the risk. So that will
3	my understanding of my causal question was	3	have to be weighed.
4	exposure to talcum powder products and ovarian	4	But I am not providing that causal link
5	cancer and whether the constituents can provide	5	between the individual constituent and ovarian
6	evidence in support or refute that association.	6	cancer.
7	So, you know, whether asbestos exposure,	7	Q. And that would be true for any of the
8	what different kinds, others will opine on that.	8	individual fragrance chemicals and heavy metals
9	Q. Do you know what a cleavage fragment	9	that may be present in the baby powder; correct?
10	is?	10	MS. PARFITT: Objection.
11	A. No. And we can go on on this kind of	11	A. I don't have that area of expertise on
12	stuff, and I'll say no.	12	individual constituents in products.
13	Q. Do you know how it differs from an	13	MR. ZELLERS: I have no further
14	asbestos fiber?	14	questions. Thank you.
15	A. No. And I'm not a mineralogist.	15	THE WITNESS: Thank you for your time.
16	Q. If I ask you a whole line of questions	16	(Discussion off the record.)
17	about different types of asbestos, you're going	17	THE WITNESS: Thank you.
18	to defer to other folks?	18	MR. ZELLERS: Thank you, Doctor.
19	A. Yes.	19	MR. KLATT: Give me a minute to get
20	Q. Is there any epidemiology	20	organized here, Doctor.
21	substantiating the theory that fragrance	21	THE WITNESS: Sure.
22	ingredients can cause ovarian cancer?	22	MR. KLATT: Are we off the record?
23	A. I'm not aware of such studies.	23	THE VIDEOGRAPHER: No.
24	Q. Is there any epidemiology	24	MR. LOCKE: Let's go off the record,
25	substantiating the theory that exposure to trace	25	then.
	Page 299		Page 301
1			
1	amounts of the heavy metals at issue can cause	1	THE VIDEOGRAPHER: Off the record,
2	amounts of the heavy metals at issue can cause ovarian cancer?	1 2	THE VIDEOGRAPHER: Off the record, 3:47 p.m.
2	ovarian cancer?	2	3:47 p.m.
2	ovarian cancer?  A. I'm not aware of you know, again, I	2 3	3:47 p.m. (A recess was taken.)
2 3 4	ovarian cancer?  A. I'm not aware of you know, again, I didn't do the evaluation, trace the specific	2 3 4	3:47 p.m.  (A recess was taken.)  THE VIDEOGRAPHER: Back on the record,
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1 ovarian cancer? 2 A. Sure. 3 Q. And I just wanted to get a better 4 understanding of what you were referring to. 5 A. Yeah. So after, sort of and I'm not 6 going to do it until this is all over, because I 7 feel that there, you know, I have access to  1 subject; correct? 2 MS. PARFITT: Objection 3 A. I mean, depending I do 4 specifics on arrangement, but the 5 you know, as long as the disclosu 6 transparent, and as long as, you k 7 funding mechanisms, what was the	
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6 going to do it until this is all over, because I 6 transparent, and as long as, you k	
reel that there, you know, I have access to runding mechanisms, what was the	
8 documents that are that are sort of protected 8 So it's not like they have commis	
9 by court order. 9 review.	
But partly what I'm thinking of is like 10 I mean, first of all, I have just	thought
there have been so many systematic reviews and 11 about it. I haven't even done it.	
meta-analyses that I was thinking more on the 12 I'll do it with my time. But you w	would have to
13 kind of like an umbrella review of all these 13 disclose that, yeah.	
reviews that I cite in my report and with, you 14 Q. But my question, and, aga	ain, I think
know, some of the rating of reviews. 15 we'll go quicker if we just focus of the rating of reviews.	
And then and that's sort of my thinking, 16 asked and the answer to that ques	
was that what I would do is synthesize the 17 But my question is: It's entire	ely
evidence, that what I do best is synthesize 18 appropriate for companies to com	tact and retain
19 the evidence from other studies in trying to 19 outside experts to advise them an	
you know, so it would be separate from, like, 20 publish articles in the literature.	
because he asked the question, would you do a 21 You've done it yourself; corre	ct?
systematic review? You know, meta-analysis. No. 22 MS. PARFITT: Objection	. Form.
Because there have been so many already. 23 You may answer.	
Q. Have you undertaken that project yet or 24 A. Yeah. I have actually bee	en, you know,
25 is this just something you're thinking of? 25 I have worked with Eli Lilly on s	
Page 303	Page 305
1 A. Yeah. I'm thinking about 1 reviews of diabetes medications.	
2 Q. I'm sorry. Let me finish. 2 And to a point of clarificatio	
This is something you're just thinking about not paid by them, but I was an exp	
4 doing in the future? 4 which is sort of a strange arranger	
5 A. In the future. But I have 5 You don't get paid, but you're still	
6 conceptualized, if I were to do that, that's what 6 But, you know, that's my area of 6	-
7 I would do. 7 yeah, companies hire and that's ho	ow science
8 Q. And if you do do that, you would be 8 works.	
9 obliged, would you not, to disclose to whatever 9 Q. And, for example, if you c	
entity, body, journal, that you submitted this 10 institution, the University of Mass	
work to, that you had been a retained, paid  11 Medical Center, about this ovarian	
expert by plaintiffs in the talc ovarian cancer 12 factors web pages that they have,	
13 litigation; correct? 13 input on that, you would disclose	
A. Yeah. And that's been my standard 14 paid plaintiffs' expert in talc ovariants.	an cancer
practice. If you go back and look at my papers, 15 litigation; correct?	
you know, my papers on SGLT2 inhibitors, I've 16 A. Well, so to do that, I don't	
disclosed that I was funded by, you know, 17 that web page came from. I didn't	
Janssen. You know, a paper on statins that I Yes, but, you know, I'm not trying	-
19 wrote last year, I was a paid expert. 19 know if you're thinking about like	
So it's just standard practice for us to do 20 example. I didn't want to change.	I was just
21 that. 21 providing them references.	
Q. And now that you bring that up, there's 22 But, yes, if I was trying to mak	
Q. And now that you bring that up, there's absolutely nothing wrong with a company like But, yes, if I was trying to mak a document that that's on, you know	
Q. And now that you bring that up, there's 22 But, yes, if I was trying to mak	ı look at my

77 (Pages 302 to 305)

	Page 306		Page 308
1	to write something up and say, you know what, it	1	on time and other considerations.
2	increases the risk of cancer, decreases, then,	2	
3	yes, I'd disclose that.	3	Q. And, again, focusing my question very specifically, the case-control studies on talc
4	Q. And just to go over that point	4	-
5	A. Yeah.	5	and ovarian cancer, the cohort studies on tale
6		6	and ovarian cancer, the meta-analysis on talc and
	Q when you wrote the editor about Up To Date, suggesting that they update their	7	ovarian cancer that you've reviewed in this case
7			and that you've cited in your expert report in
8	website regarding tale and ovarian cancer, you	8	this case, none of those are bound by a
9	did not disclose that, at that time, you were a	9	protective order that would prevent you from
10	paid retained plaintiffs' expert; is that	10	reading them, analyzing or publishing on them;
11	correct?	11	correct?
12	A. Yes. But I asked them to clarify that	12	A. None of them are restrictive.
13	this was just to update the references, if you	13	Everybody has access. I had, too.
14	look at them.	14	Q. Okay. You talked briefly about the
15	Q. Now, going back to what this	15	Centers for Disease Control this morning.
16	conceptualizing you're having of potentially one	16	A. Yes.
17	day publishing something about talc and ovarian	17	Q. Have you ever worked with them?
18	cancer, okay, that's what I'm asking about.	18	A. No. I've applied for grants with them,
19	Are we on the same page?	19	and I wasn't funded, but I'm aware of them.
20	A. Yeah.	20	Yeah.
21	Q. Wait. I just want you to know what I'm	21	Q. Have you ever conducted a
22	asking about. Okay?	22	population-based, case-control study yourself?
23	A. Okay.	23	A. Yes.
24	Q. Now, you would agree with me, you	24	Q. As principal investigator?
25	mentioned this morning there were confidentiality	25	A. Yes.
	Page 307		Page 309
1	orders in place. But you'd admit that all of the	1	Q. Have you done so for cohort studies?
2	case-control epidemiology and all the cohort	2	A. No. Not a cohort study.
3	epidemiology and all the meta-analysis that	3	Q. Could we go to Langseth, whatever
4	you've reviewed are all out there in the	4	exhibit number that is?
5	published literature; correct?	5	MR. TISI: I've got it. It's
6	A. The majority of them, studies are,	6	Exhibit 21. I've got a copy of it here.
7	yeah. I mean, Taher is not out in the	7	MS. PARFITT: Yeah. I know.
8	literature. It's still in somewhere.	8	MR. TISI: Do you mind me giving our
1 _			
9	Q. There's no there's no meta-analysis	9	
9 10	Q. There's no there's no meta-analysis cohort study or case-control study you're aware	9 10	copy?  MR. KLATT: No. Not at all.
	cohort study or case-control study you're aware		copy?
10		10	copy? MR. KLATT: No. Not at all. BY MR. KLATT:
10 11	cohort study or case-control study you're aware of that is controlled or by some sort of protective order that would limit you citing it	10 11	copy?  MR. KLATT: No. Not at all.  BY MR. KLATT:  Q. I just have a few more questions. You
10 11 12	cohort study or case-control study you're aware of that is controlled or by some sort of protective order that would limit you citing it in some sort of review; correct?	10 11 12 13	copy?  MR. KLATT: No. Not at all.  BY MR. KLATT:  Q. I just have a few more questions. You were already asked about Langseth, but I just
10 11 12 13 14	cohort study or case-control study you're aware of that is controlled or by some sort of protective order that would limit you citing it in some sort of review; correct?  MS. PARFITT: Objection. Form.	10 11 12 13 14	copy?  MR. KLATT: No. Not at all.  BY MR. KLATT:  Q. I just have a few more questions. You were already asked about Langseth, but I just have a few more questions for you.
10 11 12 13 14 15	cohort study or case-control study you're aware of that is controlled or by some sort of protective order that would limit you citing it in some sort of review; correct?  MS. PARFITT: Objection. Form.  A. So, first of all, yeah. As you know,	10 11 12 13 14 15	copy?  MR. KLATT: No. Not at all.  BY MR. KLATT:  Q. I just have a few more questions. You were already asked about Langseth, but I just have a few more questions for you.  At the time the Langseth study was
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10 11 12 13 14 15 16 17 18 19 20 21	cohort study or case-control study you're aware of that is controlled or by some sort of protective order that would limit you citing it in some sort of review; correct?  MS. PARFITT: Objection. Form.  A. So, first of all, yeah. As you know, Taher is sort of not published. So I don't know how much of the data you can use.  But in terms of protective, I don't know all the rules about what you can use and not use.  So, I mean, it's just more my unfamiliarity with the process, but nothing if you're asking the question, is something preventing me from doing	10 11 12 13 14 15 16 17 18 19 20 21 22	copy?  MR. KLATT: No. Not at all.  BY MR. KLATT:  Q. I just have a few more questions. You were already asked about Langseth, but I just have a few more questions for you.  At the time the Langseth study was published, you would agree with me, Doctor MS. PARFITT: I'm sorry, Mike. I didn't hear your question. I'm sorry.  Q. Yeah. Let me start over. MS. PARFITT: I appreciate that. Q. I'm talking about the Langseth paper that we've marked as Exhibit 21; is that correct?
10 11 12 13 14 15 16 17 18 19 20 21 22 23	cohort study or case-control study you're aware of that is controlled or by some sort of protective order that would limit you citing it in some sort of review; correct?  MS. PARFITT: Objection. Form.  A. So, first of all, yeah. As you know, Taher is sort of not published. So I don't know how much of the data you can use.  But in terms of protective, I don't know all the rules about what you can use and not use.  So, I mean, it's just more my unfamiliarity with the process, but nothing if you're asking the question, is something preventing me from doing that? No.	10 11 12 13 14 15 16 17 18 19 20 21 22 23	copy?  MR. KLATT: No. Not at all.  BY MR. KLATT:  Q. I just have a few more questions. You were already asked about Langseth, but I just have a few more questions for you.  At the time the Langseth study was published, you would agree with me, Doctor MS. PARFITT: I'm sorry, Mike. I didn't hear your question. I'm sorry.  Q. Yeah. Let me start over.  MS. PARFITT: I appreciate that.  Q. I'm talking about the Langseth paper that we've marked as Exhibit 21; is that correct? It was published in 2008 by the IARC working
10 11 12 13 14 15 16 17 18 19 20 21	cohort study or case-control study you're aware of that is controlled or by some sort of protective order that would limit you citing it in some sort of review; correct?  MS. PARFITT: Objection. Form.  A. So, first of all, yeah. As you know, Taher is sort of not published. So I don't know how much of the data you can use.  But in terms of protective, I don't know all the rules about what you can use and not use.  So, I mean, it's just more my unfamiliarity with the process, but nothing if you're asking the question, is something preventing me from doing	10 11 12 13 14 15 16 17 18 19 20 21 22	copy?  MR. KLATT: No. Not at all.  BY MR. KLATT:  Q. I just have a few more questions. You were already asked about Langseth, but I just have a few more questions for you.  At the time the Langseth study was published, you would agree with me, Doctor MS. PARFITT: I'm sorry, Mike. I didn't hear your question. I'm sorry.  Q. Yeah. Let me start over. MS. PARFITT: I appreciate that. Q. I'm talking about the Langseth paper that we've marked as Exhibit 21; is that correct?

78 (Pages 306 to 309)

	Page 310		Page 312
1	the group is much larger than these folks.	1	it, in and of itself, was not statistically
2	Q. Well, these happened to be	2	significant; correct?
3	epidemiologists on the IARC working group;	3	MS. PARFITT: Object to the form.
4	correct?	4	A. Yes. But it was consistent with the
5	A. I don't know all their qualifications.	5	overall estimates.
6	Q. Do you know any of those people	6	Q. And the cohort study didn't show an
7	personally who are listed as authors on	7	increased risk. And the two cohort studies since
8	Exhibit 21?	8	Langseth have not shown an increased risk of
9	A. No.	9	ovarian cancer in talc users; correct?
10	Q. I'll represent to you that they're	10	MS. PARFITT: Objection. Misstates the
11	epidemiologists. You would agree with me, that	11	evidence.
12	if you turn over to Page 2, they listed 14	12	A. I see that, A, two of the cohort
13	population-based, case-control studies up at the	13	studies have showed an excess risk, which is not
14	top, and then they had six more hospital-based,	14	statistically significant. One study has showed
15	case-control studies; correct?	15	statistically significant increased risk, and the
16	A. Yes.	16	third studies have showed, you know, risk
17	Q. At this time, there was one cohort	17	estimates lower than one, but their upper bounds
18	study all on the subject of talc and ovarian	18	are entirely consistent with what we see here and
19	cancer at the time; correct?	19	subsequent to this.
20	A. Yes.	20	Q. So the population-based, case-control
21	Q. You would admit that the	21	studies collectively show an increased risk. But
22	population-based, case-control studies did not,	22	they're inconsistent; correct?
23	consistently across the board, show a	23	A. No.
24	statistically significant increased risk	24	MS. PARFITT: Objection.
25	according to the table in Exhibit 21, the	25	A. I mean, let's go to Penninkilampi. I
	Page 311		Page 313
1		1	Page 313 mean, they clearly opine that
1 2	Page 311  Langseth paper. Some were statistically significant, and others were not; correct?	1 2	
	Langseth paper. Some were statistically		mean, they clearly opine that
2	Langseth paper. Some were statistically significant, and others were not; correct?	2	mean, they clearly opine that Q. I'm asking you about Langseth.
2	Langseth paper. Some were statistically significant, and others were not; correct?  A. Yeah. But I mean, I don't view	2 3	mean, they clearly opine that Q. I'm asking you about Langseth. A. Why are we looking at 2008 when we are
2 3 4	Langseth paper. Some were statistically significant, and others were not; correct?  A. Yeah. But I mean, I don't view statistical significance as	2 3 4	mean, they clearly opine that Q. I'm asking you about Langseth. A. Why are we looking at 2008 when we are in 2019?
2 3 4 5	Langseth paper. Some were statistically significant, and others were not; correct?  A. Yeah. But I mean, I don't view statistical significance as Q. Doctor A areas of consistency. Q. Doctor, I just asked whether they were	2 3 4 5	mean, they clearly opine that Q. I'm asking you about Langseth. A. Why are we looking at 2008 when we are in 2019? Q. Because I'm asking the questions.
2 3 4 5 6	Langseth paper. Some were statistically significant, and others were not; correct?  A. Yeah. But I mean, I don't view statistical significance as Q. Doctor A areas of consistency.	2 3 4 5 6	mean, they clearly opine that Q. I'm asking you about Langseth. A. Why are we looking at 2008 when we are in 2019? Q. Because I'm asking the questions. A. Okay.
2 3 4 5 6 7	Langseth paper. Some were statistically significant, and others were not; correct?  A. Yeah. But I mean, I don't view statistical significance as Q. Doctor A areas of consistency. Q. Doctor, I just asked whether they were	2 3 4 5 6 7	mean, they clearly opine that Q. I'm asking you about Langseth. A. Why are we looking at 2008 when we are in 2019? Q. Because I'm asking the questions. A. Okay. Q. You would agree with me that, of the three study designs, cohort studies, hospital-based, case-control studies and
2 3 4 5 6 7 8	Langseth paper. Some were statistically significant, and others were not; correct?  A. Yeah. But I mean, I don't view statistical significance as Q. Doctor A areas of consistency. Q. Doctor, I just asked whether they were statistically significant.	2 3 4 5 6 7 8	mean, they clearly opine that Q. I'm asking you about Langseth. A. Why are we looking at 2008 when we are in 2019? Q. Because I'm asking the questions. A. Okay. Q. You would agree with me that, of the three study designs, cohort studies,
2 3 4 5 6 7 8 9	Langseth paper. Some were statistically significant, and others were not; correct?  A. Yeah. But I mean, I don't view statistical significance as Q. Doctor A areas of consistency. Q. Doctor, I just asked whether they were statistically significant. A. No. All of them were not statistically significant. Q. And we're talking about the 14	2 3 4 5 6 7 8 9 10	mean, they clearly opine that Q. I'm asking you about Langseth. A. Why are we looking at 2008 when we are in 2019? Q. Because I'm asking the questions. A. Okay. Q. You would agree with me that, of the three study designs, cohort studies, hospital-based, case-control studies and population-based, case-control studies, only one of those three study designs shows an overall
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	Langseth paper. Some were statistically significant, and others were not; correct?  A. Yeah. But I mean, I don't view statistical significance as Q. Doctor A areas of consistency. Q. Doctor, I just asked whether they were statistically significant. A. No. All of them were not statistically significant. Q. And we're talking about the 14 population-based, case-control studies in the Langseth paper as of 2008; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	mean, they clearly opine that Q. I'm asking you about Langseth. A. Why are we looking at 2008 when we are in 2019? Q. Because I'm asking the questions. A. Okay. Q. You would agree with me that, of the three study designs, cohort studies, hospital-based, case-control studies and population-based, case-control studies, only one of those three study designs shows an overall increased risk of ovarian cancer in talc users; correct?
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79 (Pages 310 to 313)

	Page 314		Page 316
1	correct?	1	things you had reviewed was an Exhibit 47 to
2	A. Sorry. Just give me a second.	2	Imerys employee Julie Pier's deposition.
3	Yeah. The Bradford Hill overviews as one.	3	Do you recall that?
4	Q. And you know, Sir Bradford Hill himself	4	A. Yes. If you can show me that.
5	said that, in evaluating consistency, you have to	5	MR. KLATT: Sure.
6	look at consistency across different study	6	THE WITNESS: Thank you.
7	designs; correct?	7	MR. KLATT: I'm sorry. I'm sorry.
8	A. Yeah. And times and places and other	8	THE WITNESS: Exhibit
9	things.	9	MR. KLATT: Yeah. Let's mark it as the
10	Q. But I'm correct that Dr. Bradford or	10	next exhibit. And that would be 33; is that
11	Sir Bradford Hill said that you have to look at	11	correct?
12	consistency across different study designs;	12	MS. PARFITT: 32.
13	correct?	13	COURT REPORTER: Here is 32 that you
14	A. That's what I state in my testimony, as	14	haven't used.
15	well in my report cites that specific phrase,	15	MR. KLATT: Let me do this. Yes. That
16	consistency across study designs, times and	16	will be 32.
17	places. So I am not you know, I am, in fact,	17	(Chart marked Exhibit 32.)
18	quoting him when I cite that.	18	MR. TISI: The chart?
19	Q. You said, on Page 15 of your report,	19	MR. KLATT: Yes.
20	that, "Talc-based body powders are used	20	BY MR. KLATT:
21	habitually for months or years rather than just a	21	Q. I'm going to show you what's been
22	single application"; correct?	22	marked as Exhibit 32 to this deposition. But for
23	A. Where is that?	23	future record references, it also has, in the
24	MS. PARFITT: Page 15.	24	upper right-hand corner, a photocopy, Exhibit
25	Q. Page 15.	25	No. 47; correct?
	Page 315		Daga 217
	5		Page 317
1		1	A. Yeah.
1 2	A. Where is that? I'm sorry. Which part of it? 15. I know I have 15. Is it the last	1 2	
	A. Where is that? I'm sorry. Which part of it? 15. I know I have 15. Is it the last		A. Yeah.
2	A. Where is that? I'm sorry. Which part	2	<ul><li>A. Yeah.</li><li>Q. Exhibit 47 was the exhibit number at</li></ul>
2	A. Where is that? I'm sorry. Which part of it? 15. I know I have 15. Is it the last paragraph or	2 3	<ul><li>A. Yeah.</li><li>Q. Exhibit 47 was the exhibit number at</li><li>Ms. Pier's deposition, and Exhibit 32 is the</li></ul>
2 3 4	A. Where is that? I'm sorry. Which part of it? 15. I know I have 15. Is it the last paragraph or MS. PARFITT: Yeah.	2 3 4	A. Yeah. Q. Exhibit 47 was the exhibit number at Ms. Pier's deposition, and Exhibit 32 is the exhibit number we're marking this today; correct?
2 3 4 5	A. Where is that? I'm sorry. Which part of it? 15. I know I have 15. Is it the last paragraph or MS. PARFITT: Yeah. A. I don't see okay. Yeah.	2 3 4 5	<ul> <li>A. Yeah.</li> <li>Q. Exhibit 47 was the exhibit number at</li> <li>Ms. Pier's deposition, and Exhibit 32 is the exhibit number we're marking this today; correct?</li> <li>A. Okay.</li> </ul>
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80 (Pages 314 to 317)

	Page 318		Page 320
1	Q. And where on that first one, and we're	1	on your report where I think you refer to it.
2	looking at the very first line across the top of	2	A. I know it's in the biologic
3	Exhibit 32	3	plausibility section somewhere.
4	A. Sure.	4	Q. Look on page I believe it's Page 61
5	Q where in the world does it say that	5	of your report.
6	that was a sample of talc that ended up in	6	A. Yes.
7	Johnson & Johnson's talc-based body powder	7	Q. No. I'm sorry. It's Page 59 of your
8	products?	8	report. And it's the third paragraph down.
9	A. Well, my understanding, and I can share	9	A. Mm-hmm.
10	that, that this was this was that that	10	Q. And you say, in the middle of the third
11	testimony was given that this was a testing of	11	paragraph, "In studies of human mesothelial
12	mines that was being mined by Imerys or I	12	cells, both nonfibrous talc and asbestos have
13	mean, that contained asbestos.	13	shown evidence of genotoxicity," and the
14	Whether it ended up in baby powder was not	14	reference is 109, and my understanding is
15	the question. The question was: Does talc	15	reference 109 is the Shukla paper published in
16	contain asbestos?	16	2009; correct?
17	Q. Did plaintiffs' counsel ask you to make	17	A. Where are you referring? I'm sorry.
18	that assumption?	18	In Page 59?
19	A. No. No.	19	Q. Page 59 of your report, third
20	Q. Okay. Well, then, I'm confused,	20	paragraph.
21	because Imerys and its predecessors have tested	21	A. Yeah.
22	literally thousands of samples of talc from	22	Q. Second sentence.
23	competitors, from their own mines, from mines	23	A. Yeah. It says here, should be Shukla.
24	that are never used for cosmetic purposes or baby	24	Yeah.
25	powder, so how can you tell me that the first	25	Q. Did you read the Shukla paper?
	Page 319		Page 321
1	sample on Exhibit 32 has anything to do with baby	1 1	A. I read you know, I didn't read it
		1	A. I lead you know, I didn't lead it
2	powder?	2	line by line. But, yes, I read it.
2			line by line. But, yes, I read it.
	powder?	2	
3	powder?  A. Well, I'm not telling you anything to	2 3	line by line. But, yes, I read it. Q. You know the Shukla paper has nothing
3 4	powder?  A. Well, I'm not telling you anything to do with baby powder. My question is that, you	2 3 4	line by line. But, yes, I read it.  Q. You know the Shukla paper has nothing to do with genotoxicity; correct?
3 4 5	powder?  A. Well, I'm not telling you anything to do with baby powder. My question is that, you know that what constitutes talcum powder	2 3 4 5	line by line. But, yes, I read it.  Q. You know the Shukla paper has nothing to do with genotoxicity; correct?  A. I mean, we can look at it.
3 4 5 6	powder?  A. Well, I'm not telling you anything to do with baby powder. My question is that, you know that what constitutes talcum powder products. And based on this and, you know, talc	2 3 4 5 6	line by line. But, yes, I read it.  Q. You know the Shukla paper has nothing to do with genotoxicity; correct?  A. I mean, we can look at it.  Q. Sure. It's about gene expression;
3 4 5 6 7	powder?  A. Well, I'm not telling you anything to do with baby powder. My question is that, you know that what constitutes talcum powder products. And based on this and, you know, talc is mined together with all these other particles,	2 3 4 5 6 7	line by line. But, yes, I read it.  Q. You know the Shukla paper has nothing to do with genotoxicity; correct?  A. I mean, we can look at it.  Q. Sure. It's about gene expression; correct?
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Well, I'm not telling you anything to do with baby powder. My question is that, you know that what constitutes talcum powder products. And based on this and, you know, talc is mined together with all these other particles, I wanted to know, what are the results.  And at least based on my understanding of these results, again, I'm not a mineralogist, they can argue whether the amount of asbestos is significant or, you know, these fibers, chromium, cobalt, nickel are significant. My understanding is that these particles are present.  Q. Can you tell me, based on your own knowledge or expertise, that any sample listed on Exhibit 32 was from talc that ended up in Johnson & Johnson's baby powder or Shower to Shower talcum powder products?  A. No. I cannot.  Q. Okay. You referred in your report to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	line by line. But, yes, I read it.  Q. You know the Shukla paper has nothing to do with genotoxicity; correct?  A. I mean, we can look at it. Q. Sure. It's about gene expression; correct?  MS. PARFITT: Let's take a moment, Mr. Klatt, see if he can look at the study here. Q. Do you have it handy, Doctor? A. No. I don't.  MS. PARFITT: What is he referencing, 109?  A. Shukla. I mean, it might be in my files.  Q. Well, I apologize. I thought I brought an extra copy, but I don't think I have one with me.  (Discussion off the record.) Q. Well, just look at the title. The title is "Alterations in Gene Expression in Human
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Well, I'm not telling you anything to do with baby powder. My question is that, you know that what constitutes talcum powder products. And based on this and, you know, talc is mined together with all these other particles, I wanted to know, what are the results.  And at least based on my understanding of these results, again, I'm not a mineralogist, they can argue whether the amount of asbestos is significant or, you know, these fibers, chromium, cobalt, nickel are significant. My understanding is that these particles are present.  Q. Can you tell me, based on your own knowledge or expertise, that any sample listed on Exhibit 32 was from talc that ended up in Johnson & Johnson's baby powder or Shower to Shower talcum powder products?  A. No. I cannot.  Q. Okay. You referred in your report to the Shukla paper; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	line by line. But, yes, I read it.  Q. You know the Shukla paper has nothing to do with genotoxicity; correct?  A. I mean, we can look at it. Q. Sure. It's about gene expression; correct?  MS. PARFITT: Let's take a moment, Mr. Klatt, see if he can look at the study here. Q. Do you have it handy, Doctor? A. No. I don't.  MS. PARFITT: What is he referencing, 109? A. Shukla. I mean, it might be in my files. Q. Well, I apologize. I thought I brought an extra copy, but I don't think I have one with me.  (Discussion off the record.) Q. Well, just look at the title. The title is "Alterations in Gene Expression in Human Mesothelial Cells Correlates with Neural

81 (Pages 318 to 321)

	Page 322		Page 324
1	Q. Gene expression is something that	1	common in these lawsuits, wasn't associated with
2	occurs in our bodies every day; correct?	2	pelvic inflammatory disease; correct?
3	Trillions of times every day; correct?	3	A. Again, I don't remember the papers.
4	A. Yeah. Yeah.	4	Sorry.
5	Q. And changes in gene expression, in and	5	Q. All right. Well, it's on Page 58 of
6	of themselves, don't establish genotoxicity;	6	your report and it's reference 122.
7	correct?	7	A. Which page of my report?
8	A. Yeah. And I'm not again, this, you	8	Q. Page 58 of your report that cites
9	know, in the section on biologic plausibility,	9	reference 122.
10	I'm not making this argument that tale is an	10	MS. PARFITT: Here's the article.
11	established mutagen and, you know, whether it's a	11	Q. Do you see the reference?
12	genotoxic or nongenotoxic carcinogen. I'm just	12	A. Yeah. Yeah.
13	citing the studies.	13	Q. Do you see the reference in your
14	So, I mean, again, I don't have that	14	report?
15	expertise, and, you know, does it provide	15	A. Sure.
16	evidence for or against biological plausibility	16	Q. And reference 122 is to the Rasmussin
17	mechanisms.	17	paper from 2017 on pelvic inflammatory disease
18	Q. Okay. But you don't have the expertise	18	and ovarian cancer; correct?
19	to judge that; correct?	19	A. Yeah. And my citation is correct. I
20	MS. PARFITT: Objection.	20	mean, about borderline ovarian. I don't misquote
21	A. No. I have expertise to judge whether	21	the study.
22	these studies suggest evidence of, you know,	22	Q. I didn't say you misquoted it, but the
23	changes and we should probably just look at it	23	study does stand for the proposition that the
24	give me a second.	24	most common form of ovarian cancer, both in the
25	Q. Sure.	25	U.S. and in these lawsuits, high-grade serous
	D 202		
	Page 323		Page 325
1	MS. PARFITT: Give me a second.	1	Page 325 ovarian cancer is not associated with pelvic
1 2	MS. PARFITT: Give me a second.	1 2	ovarian cancer is not associated with pelvic
	MS. PARFITT: Give me a second. Q. My specific question is you cited		ovarian cancer is not associated with pelvic inflammatory disease; correct?
2	MS. PARFITT: Give me a second. Q. My specific question is you cited Shukla for evidence of genotoxicity, but it says	2	ovarian cancer is not associated with pelvic inflammatory disease; correct?  A. Where does it show that? I didn't
2 3 4	MS. PARFITT: Give me a second. Q. My specific question is you cited Shukla for evidence of genotoxicity, but it says nothing whatsoever about genotoxicity, does it?	2 3 4	ovarian cancer is not associated with pelvic inflammatory disease; correct?  A. Where does it show that? I didn't Q. Can you go to the "Discussion" section.
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	Page 326		Page 328
1	paragraph starts with "to our knowledge";	1	Q. So the paper you cited, the 2017
2	correct?	2	Rasmussin paper on pelvic inflammatory disease
3	A. Yeah.	3	and ovarian cancer is inconsistent with the
4	Q. Okay. Go down one, two, three, to the	4	theory that chronic inflammation causes
5	fourth paragraph starting with "in the present	5	high-grade serous ovarian cancer; correct?
6	study"?	6	A. Let's go to Paragraph 3.
7	A. Sure.	7	Q. Could you just answer my question?
8	Q. And in that paragraph, tell me if I	8	A. Yeah. I'm trying to.
9	correctly quote this sentence.	9	MS. PARFITT: Objection.
10	"Conversely, no convincing associations	10	A. No. It isn't inconsistent.
11	between PID," which is pelvic inflammatory	11	Because if you look at Paragraph 3, they
12	disease, "and the risk of high-grade serous,	12	state, "Furthermore, we observed similarly
13	mucinous, clear cell or endometrioid ovarian	13	increased risks of serous and mucinous borderline
14	cancer were noted in the main analysis."	14	tumors associated with PID status. Furthermore,"
15	Did I read that correctly?	15	and they also state, "Sensitivity analysis
16	A. Yes.	16	revealed statistically significant increased risk
17	Q. And then if you go down to the very	17	of low-grade serous and endometrial when using
18	next paragraph that begins with "nevertheless."	18	data from the North American"
19	A. Yeah. I see that, but I	19	So I don't think your and concerning the
20	Q. Wait. Wait.	20	histologic subtypes, indications of risk of
21	A. No. No. I need to answer your	21	low-grade serous cancers were noted in the main
22	question.	22	analysis. I wasn't disaggregating. But this
23	Q. I'm just asking you, first of all, if	23	entirely consistent with what I quote here, that
24	I'm reading this correctly.	24	you increase serous type and you increase
25	A. Sure.	25	low-grade type and you increase histologic.
	Page 327		Page 329
1	Page 327  Q. In the next paragraph that begins with	1	Page 329 You are trying to disaggregate this into a
1 2		1 2	
	Q. In the next paragraph that begins with		You are trying to disaggregate this into a
2	Q. In the next paragraph that begins with "nevertheless," do you see what I'm talking	2	You are trying to disaggregate this into a high-grade serous. I don't know what's in the
2	Q. In the next paragraph that begins with "nevertheless," do you see what I'm talking about?	2 3	You are trying to disaggregate this into a high-grade serous. I don't know what's in the lawsuit. I'm really not opining on
2 3 4	Q. In the next paragraph that begins with "nevertheless," do you see what I'm talking about?  A. Yeah.	2 3 4	You are trying to disaggregate this into a high-grade serous. I don't know what's in the lawsuit. I'm really not opining on Q. I'm not trying to disaggregate anything, Doctor. I'm saying Rasmussin, the study that you
2 3 4 5	<ul><li>Q. In the next paragraph that begins with "nevertheless," do you see what I'm talking about?</li><li>A. Yeah.</li><li>Q. There's a sentence that says,</li></ul>	2 3 4 5	You are trying to disaggregate this into a high-grade serous. I don't know what's in the lawsuit. I'm really not opining on Q. I'm not trying to disaggregate anything, Doctor. I'm saying Rasmussin, the
2 3 4 5 6	Q. In the next paragraph that begins with "nevertheless," do you see what I'm talking about?  A. Yeah. Q. There's a sentence that says, midparagraph, "In contrast, no associations	2 3 4 5 6	You are trying to disaggregate this into a high-grade serous. I don't know what's in the lawsuit. I'm really not opining on Q. I'm not trying to disaggregate anything, Doctor. I'm saying Rasmussin, the study that you
2 3 4 5 6 7	Q. In the next paragraph that begins with "nevertheless," do you see what I'm talking about?  A. Yeah. Q. There's a sentence that says, midparagraph, "In contrast, no associations between pelvic inflammatory disease and	2 3 4 5 6 7	You are trying to disaggregate this into a high-grade serous. I don't know what's in the lawsuit. I'm really not opining on Q. I'm not trying to disaggregate anything, Doctor. I'm saying Rasmussin, the study that you A. Yeah. Q. The study that you chose to cite A. Sure.
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	Page 330		Page 332
1	serous that doesn't occur very often. My	1	cancer. So if we disaggregate it, then we have
2	question is about high-grade serous ovarian	2	to disaggregate the way they have defined it.
3	cancer in the evidence from the Rasmussin paper,	3	Q. And when we disaggregate, you come to
4	and they say clearly twice, that pelvic	4	the conclusion that inflammation is associated
5	inflammatory disease is not associated with	5	with borderline ovarian cancer. But, in
6	high-grade serous ovarian cancer; is that	6	fairness, you have to come to the conclusion that
7	correct?	7	inflammation is not associated with high-grade
8	A. That's what they state in the study.	8	serous ovarian cancer?
9	But they also state clearly that serous ovarian	9	MS. PARFITT: Objection.
10	cancer is associated with PID status. So that's	10	Q. If you're being objective; correct?
11	also clearly stated.	11	MS. PARFITT: Objection. Misstates
12	Q. And if, indeed, as they state, there is	12	testimony.
13	no association between high-grade serous ovarian	13	A. I am being objective. I am providing
14	cancer and pelvic inflammatory disease, that's	14	that they conclude, not I conclude, that, you
15	inconsistent with the theory that inflammation	15	know, inflammation is PID, you know, it's just
16	causes high-grade serous ovarian cancer; correct?	16	one aspect of inflammation. PID is associated
17	MS. PARFITT: Objection. Form.	17	with serous ovarian cancer. And, yes, it is not
18	A. So, again, you know, first of all, you	18	associated with high-grade epithelial ovarian
19	know, I other people will opine to the	19	cancer.
20	biologic sort of arguments about inflammation and	20	Q. You talked with Mr. Zellers earlier
21	ovarian cancer. And I did not disaggregate	21	today about recall bias, correct, and how it can
22	specific, and I don't think this study is	22	operate in case-control studies?
23	inconsistent with what I state here. And I note	23	A. I don't recall the details.
24	that borderline ovarian cancer.	24	Q. But you recall the subject was
25	So this is entirely consistent with the	25	discussed
	Page 331		Page 333
1	inflammation hypothesis. And I just, you know	1	A. Yes.
2	Q. In your report, you cited what you	2	Q correct?
3	thought was consistent with the inflammation	3	A. Yes. And I'm going to take a break in
4			
4	theory, but you didn't cite the evidence from	4	a minute.
4 5	Rasmussin that was inconsistent with the	4 5	a minute.  Q. Sure. Do you know if, in any of these
5	Rasmussin that was inconsistent with the	5	Q. Sure. Do you know if, in any of these
5 6	Rasmussin that was inconsistent with the inflammation theory; correct?	5 6	Q. Sure. Do you know if, in any of these case-control studies well, let me back up.
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	Page 334		Page 336
1	mouth what might cause her ovarian cancer, that	1	eliminate for the possibility of recall bias.
2	may bias the results; correct?	2	Others may design it differently.
3	MS. PARFITT: Objection.	3	THE WITNESS: I'm going to take a
4	A. There's lots of different questions you	4	break.
5	could ask them. You know, I would have, if I had	5	MR. KLATT: Sure.
6	designed a study, I would have asked many other	6	THE VIDEOGRAPHER: Off the record,
7	questions.	7	4:30 p.m.
8	Q. And would you have asked that one, "Do	8	(A recess was taken.)
9	you have preconceived notions as to what might	9	THE VIDEOGRAPHER: Back on the record.
10	have caused your ovarian cancer," before you	10	4:36 p.m.
11	entered the study?	11	BY MR. KLATT:
12	A. I don't you know, I don't I	12	Q. Doctor, are you board certified in
13	haven't thought about that conceptual or new	13	epidemiology?
14	study. I'm not sure that is that important	14	A. No.
15	question to ask.	15	Q. Are you a member of the American
16	Q. It wouldn't be an important question to	16	College of Epidemiology?
17	ask women entering a study, a case-control	17	A. No.
18	study	18	Q. Are you a member of the Society for
19	A. Sure.	19	Epidemiologic Research?
20	Q women who have ovarian cancer, "Do	20	A. No.
21	you have a preconceived notion about what caused	21	MR. KLATT: All right. I'm going to
22	your ovarian cancer?"	22	turn it over to Mr. Locke. Thank you for your
23	A. You know, I've done designed	23	time.
24	case-control studies of etiology cases and	24	THE WITNESS: Thank you.
25	outcomes. I've never asked the participants	25	THE VIDEOGRAPHER: Off the record,
	Page 335		Page 337
1	Page 335 about what is your preconceived notions about	1	Page 337 4:36 p.m.
1 2		1 2	
	about what is your preconceived notions about		4:36 p.m.
2	about what is your preconceived notions about certain outcomes.	2	4:36 p.m. (A recess was taken.)
2	about what is your preconceived notions about certain outcomes.  I mean, I'm just trying to understand, why	2 3	4:36 p.m.  (A recess was taken.)  THE VIDEOGRAPHER: Back on the record,
2 3 4	about what is your preconceived notions about certain outcomes.  I mean, I'm just trying to understand, why would you ask that, because	2 3 4	4:36 p.m.  (A recess was taken.)  THE VIDEOGRAPHER: Back on the record, 4:38 p.m.
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2 3 4 5 6	about what is your preconceived notions about certain outcomes.  I mean, I'm just trying to understand, why would you ask that, because  Q. Because you're trying to eliminate bias from the study; correct?	2 3 4 5 6	4:36 p.m.  (A recess was taken.)  THE VIDEOGRAPHER: Back on the record, 4:38 p.m.  CROSS-EXAMINATION BY MR. LOCKE:
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	Page 338		Page 340
1	today, have you worked with any of the	1	A. I remember asking about this specific
2	plaintiffs' lawyers with whom you've had dealings	2	trial. I have not asked for other trial
3	in talc?	3	testimony, I don't think.
4	A. Yeah. I mentioned that I worked with	4	Q. When you say "this specific trial,"
5	Attorney Restaino in the atorvastatin that is	5	what do you mean?
6	listed on my testimony.	6	A. When I said you know, I said, in
7	Q. Anyone else?	7	this litigation, have epidemiology testimony been
8	A. No.	8	submitted. And I have asked for it. Yeah.
9	Q. Have you worked with the Beasley Allen	9	Q. Would it be relevant to you that other
10	firm?	10	scientists have analyzed the very same issues
11	A. They're not I don't know if they're	11	that are encompassed in your report and testified
12	part of this talc. The name sounds familiar. I	12	on behalf of defendants in other talc litigation?
13	just don't know the name of the lawyers.	13	A. Yeah. And as you see that, I have not
14	Q. Right. They're part of the lead	14	even had a chance to review the expert report
15 16	plaintiffs' counsel in this multi-district litigation.	15 16	of on behalf of the plaintiffs that were submitted in the list.
16 17	A. But I just have had correspondence with	17	So, yes, it will be nice to do that. A, how
18	these lawyers. So, you know, I may have had	18	much time; and, B, you know, I think it would
19	received, I don't know, documents or I don't	19	probably be more prudent to wait for the
20	know if invoices or something that may have. But	20	epidemiologists on this particular case.
21	I don't I haven't, like, corresponded with the	21	But, you know, as you said, I haven't even
22	lawyers of Beasley Allen.	22	had the chance to review the plaintiffs' experts.
23	Q. What I'm asking about is whether you	23	And, you know, I asked for defendants' expert,
24	had worked with the Beasley Allen firm prior to	24	you know, report.
25	this tale litigation.	25	Q. You asked for defendants' expert
	<u> </u>		
	Page 339		Page 341
1	Page 339  A. I have listed the you know,	1	Page 341 reports in this litigation.
1 2	A. I have listed the you know, listed the cases I worked for. I don't remember	1 2	
	A. I have listed the you know, listed the cases I worked for. I don't remember the name of the counsels and, you know, who were		reports in this litigation.
2	A. I have listed the you know, listed the cases I worked for. I don't remember	2	reports in this litigation.  A. Sure.
2	A. I have listed the you know, listed the cases I worked for. I don't remember the name of the counsels and, you know, who were on the firms. So if it ended up that they were involved in Viagra or something else, that's just	2 3	reports in this litigation.  A. Sure.  Q. But you didn't ask for defendants' expert reports, deposition transcripts or trial testimony in the prior talc litigation?
2 3 4 5 6	A. I have listed the you know, listed the cases I worked for. I don't remember the name of the counsels and, you know, who were on the firms. So if it ended up that they were involved in Viagra or something else, that's just a recollection issue.	2 3 4	reports in this litigation.  A. Sure. Q. But you didn't ask for defendants' expert reports, deposition transcripts or trial testimony in the prior talc litigation?  A. How do I know? I mean, I'm not very
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I have listed the you know, listed the cases I worked for. I don't remember the name of the counsels and, you know, who were on the firms. So if it ended up that they were involved in Viagra or something else, that's just a recollection issue.  Q. Okay. Mr. Klatt asked you about materials authored by defense experts. Let me elaborate on that a little bit.  Are you aware that various defense experts authored reports in connection with prior talc litigation?  A. No. I'm not aware.  Q. Are you aware that there were prior talc trials?  A. I mean, I have seen it in the news that I don't know if they're in state court, federal court, you know. I see it in the news.  Q. Did you  A. California or something. Yeah. I'm not aware.  Q. Did you ask for the testimony of any	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	reports in this litigation.  A. Sure.  Q. But you didn't ask for defendants' expert reports, deposition transcripts or trial testimony in the prior talc litigation?  A. How do I know? I mean, I'm not very familiar with how these, you know, different trials are occurring, what you can share, which attorneys are involved in which trials.  I'm sorry. I didn't ask for it. I know that, but I'm just not familiar with that process, what they can share.  Q. Okay. Can you go to Page 10 of your report. And I guess there are two exhibits to it, or it's referred to in two exhibits.  Are you looking at Exhibit 10 there?  A. Exhibit 10.  Q. On the front page.  MS. PARFITT: It's your report. Yes.  A. Exhibit 10. Yes.  Q. So if you could go to Page 10, I'd appreciate that. And on Page 10, you're

86 (Pages 338 to 341)

	- 240		244
	Page 342		Page 344
1	A. Yes.	1	be useful, because you couldn't find all of the
2	Q. Okay. If you would look at the	2	lung cancer cases.
3	paragraph that begins with the phrase	3	A. Yes. And that sort of applies to
4	"case-control studies."	4	Gonzalez. And it was a six-month study, and some
5	Do you see that there?	5	of the other cohort studies that were of limited
6	A. Yeah.	6	duration.
7	Q. Okay. You're explaining your opinion	7	So, yes, I mean, I don't know about the time
8	why case-control studies have some advantages	8	course exactly of lung cancer risk, but can apply
9	over cohort studies in that paragraph; is that	9	to various outcomes.
10	correct?	10	Q. Okay. So what is the latency period
11	A. No. Not necessarily. I mean, that	11	for perineal talc exposure and ovarian cancer?
12	just talks about the strength and weaknesses of	12	A. I do not have I don't know, because,
13	various studies designs. I mean, in fact, you	13	you know, I don't again, I don't elucidate the
14	know, it talks about whether, you know, that, in	14	mechanism of ovarian cancer and the precise link.
15	fact, it says exposure is ascertained	15	So I cannot tell you that X number of days after
16	retrospectively.	16	perineal talc or months after. I know that it is
17	So I'm just talking about the strength and	17	long-term. It could be months to years. And
18	limitations of various designs.	18	that's as much as I can say.
19	Q. Okay. I was using advantages and	19	Q. So your example, when you were talking
20	disadvantages.	20	about 12 months, actually, that really wouldn't
21	Is there a significant difference between	21	be a problem or we don't know whether that's a
22	those two?	22	problem or not because it could be months?
23	A. That's just the term we use. Yeah.	23	A. No.
24	Q. Okay. Now, one of the strengths, in	24	MS. PARFITT: Objection.
25	your opinion, of a case-control study, is that it	25	THE WITNESS: Sorry.
	Page 343		Page 345
1		1	
1 2	Page 343 captures the entire time period when an ovarian cancer illness could occur; is that correct?	1 2	A. So, yeah, months would be a problem.
	captures the entire time period when an ovarian cancer illness could occur; is that correct?		A. So, yeah, months would be a problem. It's mostly I mean, yes, we have some bounds,
2	captures the entire time period when an ovarian cancer illness could occur; is that correct?  A. That's not necessarily like an entire	2	A. So, yeah, months would be a problem.
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	Page 346		Page 348
1	Q. If you look at the next paragraph,	1	not even a citation. I mean, it's I feel
2	first sentence, last clause.	2	that, and we were discussing that, you know,
3	A. Yeah.	3	could a randomized trial be here conducted. And
4	Q. Other plaintiffs' experts have stated	4	to my mind, it would be unethical. So
5	in their reports that the latency period could be	5	Q. Well, yeah. But then you say,
6	decades.	6	"Defendants here have admitted this fact."
7	Would you disagree with that?	7	And so I'm just wondering what brought you
8	A. Yeah. I mean, when I say many years,	8	to that particular part midway in her deposition,
9	it could be yeah, I just	9	the second day of her deposition of a three-day
10	Q. You don't know?	10	deposition.
11	A. I don't know the precise. I don't want	11	A. Some of this has, you know it just
12	to quantify the number of years.	12	doesn't I don't know why I would, you know,
13	Q. Okay. I want to shift topics a little	13	put it but it's sort of it's even
14	bit here. You reference Linda Loretz's	14	irrelevant if you take her out of it. Because,
15	deposition transcript in I think once in your	15	you know, it's like, are we really going to do a
16	report.	16	randomized trial?
17	If you would go to Page 7, I believe it is.	17	Q. I agree with you. It's irrelevant.
18	It's in a footnote. Footnote 1.	18	A. Yeah.
19	A. Mm-hmm.	19	Q. If you could go to Page 62 of your
20	Q. Now, did you read the entirety of	20	report. You've got a caption there "Cosmetic
21	Dr. Loretz's deposition transcript?	21	Expert Review Panel Report."
22	A. Again, these are so many documents. I	22	Do you see that?
23	mean, I reviewed, you know, not but I don't	23	A. Yes.
24	know if I read the whole transcript. Yeah.	24	Q. Roman numeral XII?
25	Q. Do you know how many days she was	25	A. Yes.
	Page 347		Page 349
1	deposed?	1	Q. Do you know what the name of the
2	A. I don't recall.	2	organization is that you're referring to in that
3	Q. More than one day?	3	paragraph?
4	A. I don't know that. I'm sorry.	4	A. I don't know the name.
5	Q. So her deposition transcript, I'll	5	Q. Do you know if Dr. Loretz testified
6	represent to you, is 1,133 pages in length.	6	regarding that review?
7	Did you read all that?	7	A. If I have cited her, then I have.
8	A. No. I didn't agree that I read all of	8	Q. Well, you didn't cite her on this
9	them either. Yeah.	9	portion. That's why I'm asking about it.
10	Q. Okay. I was a little confused because	10	A. I don't know. I mean, you're asking
11	I thought you had said, for hers, that you had	11	all these different names. They're all if I
12	read the whole thing.	12	haven't cited her, then I haven't reviewed it.
13	A. No. I didn't say I had read you	13	Q. Okay. Have you heard of the Cosmetic
			v 41 . 75 . 1 . 0
14	know, I have read the transcript, but it doesn't	14	Ingredient Review?
14 15	mean that I read every, you know, precise word	15	A. Yes.
14 15 16	mean that I read every, you know, precise word and precise	15 16	<ul><li>A. Yes.</li><li>Q. Sometimes referred to as CIR?</li></ul>
14 15 16 17	mean that I read every, you know, precise word and precise Q. Do you know what her background is?	15 16 17	<ul><li>A. Yes.</li><li>Q. Sometimes referred to as CIR?</li><li>A. Yes.</li></ul>
14 15 16 17 18	mean that I read every, you know, precise word and precise Q. Do you know what her background is? A. No, I don't.	15 16 17 18	<ul><li>A. Yes.</li><li>Q. Sometimes referred to as CIR?</li><li>A. Yes.</li><li>Q. Dr. Loretz, in her deposition,</li></ul>
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14 15 16 17 18 19 20 21	mean that I read every, you know, precise word and precise Q. Do you know what her background is? A. No, I don't. Q. Do you know if she's a scientist? A. I don't remember, you know, the specifics of the transcript. Q. How is it that you picked out this	15 16 17 18 19 20 21 22	<ul> <li>A. Yes.</li> <li>Q. Sometimes referred to as CIR?</li> <li>A. Yes.</li> <li>Q. Dr. Loretz, in her deposition,</li> <li>references the CIR dozens of times, doesn't she?</li> <li>A. Again, as I said, I didn't review the</li> <li>entirety of the thousand pages.</li> <li>Q. Okay. I'm just trying to understand</li> </ul>

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	Page 350		Page 352
1	when she testified about that.	1	A. Yes.
2	A. So, as you can see, it's reference to	2	MS. PARFITT: Objection.
3	the published report, and, you know, I	3	A. But specific to tale, you would want
4	reviewed again, even that was lengthy	4	more diverse representation with gynecologists,
5	document, and, you know, I wanted to review that	5	oncologists, epidemiologists.
6	for completeness and understand that.	6	So it's not that it was a criticism of the
7	Q. Did you read the entirety of that	7	CIR review panel or whoever was on that as a
8	report?	8	dermatologist, but specific to it, did they have
9	A. As much as I can. Not every word in	9	the expertise to and maybe they did, but I'm
10	every sentence.	10	just pointing that out.
11	Q. Okay. Do you know if the FDA plays a	11	Q. So you don't know, one way or another,
12	role in the CIR's review that you're referring to	12	whether they had the expertise?
13	on Page 62 of your report?	13	A. Yeah. I mean, from my understanding,
14	A. I'm not aware of the specific	14	they didn't have expertise in carcinogenicity and
15	composition, but I know that FDA is attends or	15	epidemiology.
16	is a member or has some sort of role there.	16	Q. What do you base that on?
17	Q. Do you know who the Consumer Federation	17	A. Yeah. I mean, you know, some of the
18	of America is?	18	names that are here, they were dermatologists.
19	A. No.	19	That's sort of my understanding.
20	Q. Do you know if they play any role in	20	Q. Did you look them up and investigate
21	the CIR report?	21	what they do or what they have done in their
22	A. I don't know. And maybe it's in the	22	careers?
23	study and I can't tell you offhand who is in this	23	A. No. I have not.
24	panel.	24	Q. Okay. So you're criticizing them as
25	Q. It's also in Dr. Loretz's deposition.	25	not having the capability of doing the review,
	Page 351		Page 353
1	That's the reason I'm exploring it.		
	That's the reason i'm exploring it.	1	but you don't really know their expertise?
2	Do you know that one of the missions of the	1 2	but you don't really know their expertise?  MS. PARFITT: Objection. Misstates his
2			but you don't really know their expertise?  MS. PARFITT: Objection. Misstates his testimony.
	Do you know that one of the missions of the	2	MS. PARFITT: Objection. Misstates his
3	Do you know that one of the missions of the Consumer Federation of America is to represent	2	MS. PARFITT: Objection. Misstates his testimony.
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#### Page 354 Page 356 1 A. I don't know -- you know, I know that they asked -- this statement is about the 2 they reviewed the process and they looked at 2 question they asked. They asked the question, 3 3 studies, and I don't know if it was all that talc fiber not containing asbestos, does it 4 4 epidemiologic studies, but I think and I 5 5 understand that presumption was that talc does So if they ask the question already, we know 6 not contain asbestos. I mean, that's what -- the 6 that, they presume there was no presence of. So 7 premise they started out with. 7 it's about the question that I'm stating it. 8 Q. Well, did the epidemiologic studies 8 Q. But the epidemiologic studies, when 9 9 make a distinction between talc and its they're analyzing talc use among women, they're 10 constituents or alleged constituents? 10 not making a distinction between talc that 11 11 A. Yeah. I mean, there are -- as I cite contains or doesn't contain constituents. 12 in my report, there are -- they don't make 12 They're talking about women who use products; 13 distinctions, but they -- some of the studies --13 correct? 14 you know, some of the testimony we've discussed, 14 A. That is correct. some of the, you know, testing we've discussed, 15 Q. So if your theory is correct and talc 15 16 16 and some, you know, small publications suggest contains harmful substances in addition to talc, 17 that talc may contain asbestos. So you have 17 then the epidemiologic studies would have 18 these evidence. 18 reviewed women's exposure to those constituents; 19 19 But the CIR review was already carried out correct? 20 with the presumption that talc did not contain 20 A. Yeah. So, I mean -- so if you look at 21 21 what I've written, the review was carried out 22 22 Q. But they reviewed all of those studies under the flawed assumption that cosmetic grade, 23 that you referenced, or do you not know what they 23 you know, talc was -- did not contain that. And 24 reviewed? 24 also limited to tale that did not contain. And 25 MS. PARFITT: Objection. 25 also concluded that there was no evidence of talc Page 355 Page 357 1 1 A. I mean, I do not know every study they migration. 2 2 reviewed. I'm just providing -- I don't know I do not say that, you know, there was no --3 every study that IARC reviewed. 3 they did not review the -- the epidemiologic 4 studies of talcum powder products. That's not --4 Q. Well, you could find that out by 5 5 looking at the studies; right? you know, they reviewed it. But I'm just 6 A. There's not enough time. There's so 6 pointing out the limitations of that. 7 7 many studies in this and so many reports, so many Q. Didn't CIR cite the very same studies 8 8 assessments that -that were available as of 2013 that you cite in 9 9 Q. But you're criticizing the CIR. your report? 10 10 A. Yes. A. Yeah. 11 Q. And saying it limited its assessment. 11 MS. PARFITT: Objection. Form. A. Again, you know, I don't know if they 12 A. Sure. 12 13 13 cite evidence of biologic plausibility. I don't Q. And I just want to understand the basis 14 for that statement, and what you're saying, 14 know if they cite evidence of talc migration. I 15 testifying here today is you don't know what the 15 don't know how they interpreted the evidence 16 CIR reviewed. 16 of -- just because they cited a study does not 17 MS. PARFITT: Objection. Misstates 17 mean that they interpreted the data in the same 18 18 way that I did. testimony. 19 19 So I don't know what studies specifically in A. No. That, and we can look at it. 20 Let's look at the, you know, the --20 each section they cited. 21 Q. But you made the statement. 21 Q. Okay. One of the things that you say, 22 A. Sure. 22 "as a result of these serious methodological 23 Q. And I'm asking you, sitting here today, 23 shortcomings and funding biases." Let me ask you 24 can you say what they reviewed? 24 about that. 25 25 A. Yes. I know they reviewed -- because A. Sure.

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#### Page 358 Page 360 regulatory agency in late 2018. So things take 1 Q. Is a review that's funded by an entity 2 2 time. And, you know, people, scientists take with an interest in the outcome of that review 3 3 inherently flawed? time to come to conclusions. 4 A. No. It isn't. And this is just, you 4 Q. Okay. Let's go to Exhibit 22. A. Which is? 5 5 know, one of -- and, you know, it's a potential. 6 It should be potential for funding biases. It 6 Q. That's the Berge -- I believe that's 7 doesn't mean that just because it was funded by 7 how it's pronounced -- report? 8 PCPC or CIR, it is, you know, biased. 8 MS. PARFITT: The Berge study? 9 But yes, I mean, so, for example, my report 9 MR. LOCKE: Yes, yes. I'm sorry. 10 and testimony, because it's funded by, you know, 10 BY MR. LOCKE: 11 should be examined for potential biases. Just 11 Q. So if you could turn to Page 9, can you 12 like, you know, CIR's report should be. 12 read the last sentence right before 13 Q. I want to ask you about the timing of 13 acknowledgments, beginning with the word "several." If you could read it out loud, 14 things, because sometimes you have referred to 14 reports that were done a while ago. And in this 15 15 please. case, you do that with CIR. You say, "The 16 A. "Several aspects of our own results, 16 17 17 including the heterogeneity between case-control findings of this panel have been superseded by studies and the lack of dose-response with 18 several new epidemiologic studies," and so forth. 18 19 19 duration of and frequency of use, however, do not The line goes on. 20 20 Is it your opinion that -- well, let me ask support a causal interpretation of the 21 this way: At what point in time can we say that 21 association." 22 22 the epidemiologic studies have sort of been Q. And they're referring to the 23 completed so you could rely on that information? 23 association between talc and ovarian cancer? 24 MS. PARFITT: Objection. Form. 24 A. Yes. But other scientists, you know, 25 A. Yeah. I mean, so you rely on 25 such as Penninkilampi, have concluded otherwise, Page 359 Page 361 1 1 information from, what, 1982, Cramer one. But I that there is, you know, suggestive of a causal 2 guess the question is -- I don't know, I'm not 2 association. Health Canada has concluded 3 trying to put questions in your mouth. But I 3 otherwise, that there's evidence of causal 4 don't -- I can't -- because I evaluated the 4 association. 5 5 causal question as of 2017 and didn't arrive at Q. But here we are in 2018, there's a 6 an opinion until late 2018. 6 study that's published saying, "Does not support 7 7 I did not go year by year and, say, okay, in a causal interpretation of the association 8 2005, when IARC looked at this, could we have 8 between talc and ovarian cancer"; correct? 9 9 concluded, possible, a problem? In 2010, when A. Yes. I mean, you know --10 Langseth looked, or 2015. 10 Q. Let me just ask you: So scientists 11 So I did not segmentate it by time. And 11 disagree about this issue? 12 A. That's why we are here. If we all you're just asking, even by epidemiologic study. 12 13 It doesn't work. You have to look at the whole 13 agreed, we wouldn't be here. 14 body of evidence and come to a conclusion. 14 Q. Okay. Let me move to a different 15 Q. Isn't it true that, prior to the talc 15 topic. 16 litigation, no scientist had published an article 16 MR. TISI: How much time do we have? 17 stating that talc causes ovarian cancer? 17 How much time do we have? That's okay. Just 18 MS. PARFITT: Objection to form. 18 write it on a paper. 19 19 A. Yeah. I mean, you know, I think a lot MR. LOCKE: We're getting close. 20 of these articles have talked about -- and 20 Q. Okay. Can we go to Page 62 of your 21 scientists don't necessarily publish statements 21 report. 22 about causation, you know. 22 Now, did we already do that? Maybe we 23 You have seen that Health Canada has clearly 23 already did that. Sorry. I don't want to have 24 stated that talc causes ovarian cancer. Yes, so, 24 to do things again. 25 in fact, not even scientists, but now we have 25 A. Please don't.

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	Page 362		Page 364
1	THE VIDEOGRAPHER: 6:36.	1	don't know about the specifics, who are
2	THE WITNESS: So we have 6 minutes, 36	2	manufacturers and yeah. But I know the
3	seconds?	3	limitations of the survey.
4	Q. You have 24 minutes.	4	And even they acknowledge that the study
5	A. Oh, sorry.	5	could not prove that most or all talc-containing
6	Q. Sorry. We already did that one. So	6	cosmetic products currently marketed are likely
7	good there.	7	to be free. So even despite these whoever
8	Let's go to Page 15 of your report. We were	8	supplied them and whoever, you know, tested them.
9	talking just a moment ago about regulatory	9	MR. LOCKE: We're almost there. Then
10	entities and what they found.	10	I'll turn it back over.
11	In the middle of that paragraph or middle of	11	BY MR. LOCKE:
12	that page, there's a part that says, "Although	12	
13	the FDA conducted a survey."	13	Q. Just one second. If you could go to
14	Do you see that?	14	Page 59, please. Okay.
15	A. Yes.	l .	On Page 59, you've got a Roman numeral X
		15	followed by a Roman Numeral III. Do you see
16	Q. And they found no asbestos fibers or	16	that? Talcum powder-induced inflammation. Am I
17	structures.	17	at the right place?
18	But then you, whatever you want to call it,	18	MS. PARFITT: I'm sorry, Tom.
19	you can call it criticism or deficiencies or	19	MR. TISI: 59 of the report?
20	disadvantages, you state, "The results were	20	MR. LOCKE: Yeah.
21	limited, only four out of nine talc suppliers	21	A. It's probably 58.
22	submitted samples, and the number of products	22	Q. 58 of the report. Sorry.
23	tested was low." Is that correct?	23	MS. PARFITT: No worries.
24	A. Well, that is a correct restatement of	24	Q. Okay. So you see that, Roman numeral
25	the facts. So it is not something that I made	25	X, Roman Numeral III?
	Page 363		Page 365
1	Page 363 up. I mean, it is true that four out of nine	1	
1 2		1 2	A. Have we gone through this? I'll be
	up. I mean, it is true that four out of nine		A. Have we gone through this? I'll be happy to go through it again.
2	<ul><li>up. I mean, it is true that four out of nine suppliers</li><li>Q. J&amp;J was one of the entities that</li></ul>	2 3	A. Have we gone through this? I'll be
2	<ul><li>up. I mean, it is true that four out of nine suppliers</li><li>Q. J&amp;J was one of the entities that supplied talc to the FDA; correct?</li></ul>	2	<ul><li>A. Have we gone through this? I'll be happy to go through it again.</li><li>Q. I want to ask you about something.</li><li>A. Sure.</li></ul>
2 3 4	<ul> <li>up. I mean, it is true that four out of nine suppliers</li> <li>Q. J&amp;J was one of the entities that supplied talc to the FDA; correct?</li> <li>A. I didn't you know I didn't</li> </ul>	2 3 4	<ul><li>A. Have we gone through this? I'll be happy to go through it again.</li><li>Q. I want to ask you about something.</li><li>A. Sure.</li><li>Q. You have a statement, the first</li></ul>
2 3 4 5	up. I mean, it is true that four out of nine suppliers Q. J&J was one of the entities that supplied talc to the FDA; correct? A. I didn't you know I didn't that FDA document, you know, I'm not aware of who	2 3 4 5 6	<ul> <li>A. Have we gone through this? I'll be happy to go through it again.</li> <li>Q. I want to ask you about something.</li> <li>A. Sure.</li> <li>Q. You have a statement, the first sentence says, "Inflammation has long been</li> </ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	up. I mean, it is true that four out of nine suppliers Q. J&J was one of the entities that supplied talc to the FDA; correct? A. I didn't you know I didn't that FDA document, you know, I'm not aware of who supplied. Q. You didn't look at it. You criticized, but you didn't look at the fact that J&J submitted talc samples and product to the FDA? MS. PARFITT: Objection. Misstates his testimony. A. I reviewed the reference and I reviewed the you know, so I'm not testifying I reviewed talcum powder products and ovarian cancer. You know, and I was looking at the evidence. But I didn't look at whether J&J submitted samples or Imerys submitted samples, no. Q. And you don't know whether, then, the FDA, in fact, tested the two J&J products at issue in this litigation and found no asbestos fibers or structures in the samples? MS. PARFITT: Objection. Misstates the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Have we gone through this? I'll be happy to go through it again.  Q. I want to ask you about something. A. Sure. Q. You have a statement, the first sentence says, "Inflammation has long been understood to be an important mechanism underlying the development of ovarian cancer." Do you see that? A. Yes. Q. And then you referenced 61. And if you go to Exhibit 4, that is your list of references; correct? Well, for me, I was looking at it, because it was broken out separately. But you could see it at the back of Exhibit 10 as well. A. Yeah. Q. Do you see that, 61? A. Yeah. Q. And if you can you read the title of the reference that you're citing to there? A. The Ness study, is that? Q. Right. The Ness study.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	up. I mean, it is true that four out of nine suppliers Q. J&J was one of the entities that supplied talc to the FDA; correct? A. I didn't you know I didn't that FDA document, you know, I'm not aware of who supplied. Q. You didn't look at it. You criticized, but you didn't look at the fact that J&J submitted talc samples and product to the FDA? MS. PARFITT: Objection. Misstates his testimony. A. I reviewed the reference and I reviewed the you know, so I'm not testifying I reviewed talcum powder products and ovarian cancer. You know, and I was looking at the evidence. But I didn't look at whether J&J submitted samples or Imerys submitted samples, no. Q. And you don't know whether, then, the FDA, in fact, tested the two J&J products at issue in this litigation and found no asbestos fibers or structures in the samples?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Have we gone through this? I'll be happy to go through it again.  Q. I want to ask you about something. A. Sure. Q. You have a statement, the first sentence says, "Inflammation has long been understood to be an important mechanism underlying the development of ovarian cancer." Do you see that? A. Yes. Q. And then you referenced 61. And if you go to Exhibit 4, that is your list of references; correct? Well, for me, I was looking at it, because it was broken out separately. But you could see it at the back of Exhibit 10 as well. A. Yeah. Q. Do you see that, 61? A. Yeah. Q. And if you can you read the title of the reference that you're citing to there? A. The Ness study, is that?

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	Page 366	Page 368
1	Epithelial Inflammation in Ovarian Cancer."	1
2	Now, you're citing that for "long been	ERRATA
3	understood to be an important mechanism," but, in	2
4	fact, the first word in the title is "possible."	3 PAGE LINE CHANGE
5	A. Yeah. And you can clarify that. I	4
6	mean, this is about plausible mechanisms.	5 REASON:
7	Q. But it certainly doesn't say it's long	6
8	been understood to be an important mechanism.	7 REASON:
9	A. Well, I disagree. I mean, you know,	8
10	maybe that you can't cite all the articles for	9 REASON:
11	each statement you make. I wish I did.	10
12	But inflammation, as I understand it, is an	11 REASON:
13	important mechanism. And at least has been known	12
14	for a long time about ovarian cancer. And others	
15	can opine in more detail. Is that citation the	14 15 REASON:
16	most? Yeah, that particular citation has a	1.6
17	possible, you know, clarifier on that.	16 REASON:
18	MR. LOCKE: Okay. Let me just see if	18
19	I've got anything else here. That's all I have.	19 REASON:
20	THE WITNESS: Thank you.	1 20
21	MR. LOCKE: Thank you. Anyone else?	21 REASON:
22	MS. PARFITT: Let's take a quick break	1 22
23	and see if we have any follow-up.	23 REASON:
24	THE VIDEOGRAPHER: Off the record,	24
25	5:13 p.m.	25 REASON:
	Page 367	
1	(A recess was taken.)	1 ACKNOWLEDGMENT OF DEPONENT
2	THE VIDEOGRAPHER: Back on the record,	2
3	5:26 p.m.	I,, do 3 hereby certify that I have read the
4	MS. PARFITT: Thank you. Dr. Singh,	foregoing pages, and that the same
5	the plaintiffs have no questions. I want to	4 is a correct transcription of the answers
6	thank you for your time today.	given by me to the questions therein 5 propounded, except for the corrections or
7	We would ask that Dr. Singh read and	changes in form or substance, if any,
8	sign.	6 noted in the attached Errata Sheet.
9	MR. ZELLERS: Thank you, Doctor.	,
10	THE WITNESS: Thank you.	8 SONAL SINGH, M.D., M.P.H. DATE
11	MR. KLATT: Wait. I've got 30 seconds.	9 10
12	THE WITNESS: I want to thank everybody	11
13	for a very professional, you know I've done	12 13
14	this a couple of times. And if I have raised my	14
15	voice, it hasn't been anything personal. It's	Subscribed and sworn
16	just been trying to explain something.	15 to before me this day of, 20
17	MR. ZELLERS: Thank you, Doctor.	16
18	THE VIDEOGRAPHER: And we're off the	My commission expires:
19	record at 5:27 p.m.	18
20	(Deposition concluded at 5:27 p.m.)	Notary Public
21		19   20
22		21
23		22 23
24 25		24
		25

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1	CERTIFICATE	
2	COMMONWEALTH OF MASSACHUSETTS	
3		
	SUFFOLK, SS.	
4	I, Janet M. Sambataro, a Registered Merit	
5	Reporter and a Notary Public within and for the	
6	Commonwealth of Massachusetts do hereby certify:	
7	THAT SONAL SINGH, M.D., M.P.H., the witness	
8	whose testimony is hereinbefore set forth, was duly	
9	sworn by me and that such testimony is a true and	
10	accurate record of my stenotype notes taken in the	
11	foregoing matter, to the best of my knowledge, skill	
12	and ability; that before completion of the deposition	
13	review of the transcript was requested.	
14	I further certify that I am not related to any	
1.5	parties to this action by blood or marriage; and that	
16	I am in no way interested in the outcome of this	
17	matter.	
18	IN WITNESS WHEREOF, I have hereunto set my hand	
19	this 17th day of January, 2019.	
20	and 17 an day of January, 2017.	
21	<del></del>	
	JANET M. SAMBATARO	
22	Notary Public	
	My Commission Expires:	
23	July 16, 2021	
24	July 10, 2021	
25		
1		
1		
1		

		1	1	
A	160:15,17	61:22,25 62:2,4	255:22 293:7	agreeing
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77:15,19	accurate	80:18 81:5,10	256:7	2:8 24:9 36:9
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